

**FOREIGN OPERATIONS, EXPORT FINANCING,
AND RELATED PROGRAMS APPROPRIA-
TIONS FOR FISCAL YEAR 2005**

TUESDAY, MAY 18, 2004

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10:35 a.m., in room SD-124, Dirksen Senate Office Building, Hon. Mike DeWine presiding.

Present: Senators McConnell, DeWine, Leahy, Durbin, and Landrieu.

DEPARTMENT OF STATE

OFFICE OF THE U.S. GLOBAL AIDS COORDINATOR

STATEMENT OF HON. RANDALL L. TOBIAS, COORDINATOR

OPENING STATEMENT OF SENATOR MICHAEL DE WINE

Senator DEWINE. Let me welcome all of you today. Senator McConnell asked that I preside and begin the hearing as he currently has another commitment, but he will be here shortly to join us.

Today's subcommittee hearing on the fiscal year 2005 budget request for HIV/AIDS consists of two panels. Global HIV/AIDS Coordinator Randall Tobias will be the sole witness on the first panel, followed by DATA founding member Bono on the second.

Senator Leahy and I will make brief opening remarks, followed by Ambassador Tobias. We will then proceed to 5-minute rounds of questions and answers. At approximately 11:20, about the time we may have a vote on the floor, we will move to our second panel.

In the interest of time, I ask that our witnesses summarize their remarks and we will insert their full statements into the record. My colleagues should know that we will keep the record open for any written questions they wish to submit to our witnesses, and I request our witnesses to respond to these questions, of course, in a timely manner.

Our hearing today is a chance for us to take a look at where we have been in terms of how our funding allocations have been spent in regard to AIDS and what the plans are for the future of the President's Global AIDS Initiative. We are privileged to have before us today on the first panel Ambassador Tobias, who serves as the Coordinator of this very important initiative. He will testify on the

progress to date, as well as provide us with details on what lies ahead for the initiative.

We have an historic opportunity with the funding that has been made available for the Global AIDS Initiative. I say that because the money, that money, can and should be used not only to fight HIV/AIDS, but also to lay a foundation for improved health systems in the developing world: health care systems for children, women, and families. The money that we put forward in regard to this fight against AIDS has the potential to yield tremendous dividends in other areas of public health.

The fact is that in many of the countries that we will be spending and are spending this money for HIV/AIDS, many of these countries do not currently have a good health infrastructure. So it is really going to be impossible for us to deal with the AIDS problem without helping these countries build up that health infrastructure.

So the two are going to be linked. One of the things that I want to explore with Ambassador Tobias today is how he sees us working with these countries to build up their health infrastructures.

I think that is going to also, though, while it is a challenge, frankly it also has the benefit of providing extra dividends: that what we will end up with, we hope, in the future and what these countries and the people of these countries will end up with is not only fighting AIDS, but end up with the ability to do so much more in their health systems and end up with truly a good health system in many of these countries.

What I hope to hear from Ambassador Tobias today are his plans on how to take advantage of the \$15 billion in opportunities over the next 5 years. How can we make certain that we provide care and treatment to as many people as possible, treatment that includes the millions of children with HIV/AIDS and other infectious diseases like malaria and tuberculosis?

Mr. Ambassador, having read your testimony, I know that you will speak to the issues of procuring low-cost antiretroviral medicines for adults. But what about the children? We need to ensure that children infected with HIV are not overlooked in the drug approval and procurement process. I would ask that in your comments you clarify what your office is doing to ensure safe pediatric formulations and how your office plans to increase the number of children receiving treatment.

We know from experience that the core features of the prevention of mother-to-child transmission programs—voluntary counseling and testing, the establishment of pharmacies and drug distribution mechanisms, and the training of health care workers—all provide a sound foundation on which to build, on which to build expanded care and treatment. So I would like to hear from the Ambassador on his plans for the mother-to-child transmission program. What are your plans to increase the number of clinics capable of providing services to prevent the transmission of the virus from mother to child, especially since fewer than one percent of women have access to MTCT services in some of the most infected countries. What can we do to get more women treated before they give birth to HIV-positive babies?

Let me say again, we have \$15 billion in opportunities to help build health care infrastructures, to increase the number of children, women and families receiving treatment and care, to invest in human capital development, and to put programs in place to take care of orphans and other vulnerable children.

Let me again thank both of our witnesses for being here today, and also thank both of them for their great commitment to this cause. Ambassador Tobias, I look forward to hearing your vision on how we can take advantage of these opportunities and hearing what you have already done so far.

Let me also say that I am pleased that Bono could join us and I look forward to hearing his thoughts on debt relief. We do not know anyone else who has really had the vision in this area and who has captured the attention of the public, not only in the United States but around the world, and we salute him for his great work as well.

Let me at this point turn to Senator Leahy, the ranking member of this committee, who has also been just a great leader in this anti-AIDS work. Senator Leahy, thank you.

OPENING STATEMENT OF SENATOR PATRICK J. LEAHY

Senator LEAHY. Thank you, Mr. Chairman.

You know, it is interesting, some of the odd couplings in the Senate. Not only is Senator DeWine a close personal friend, but we have, coming from different parties and different philosophical spectrums, we have worked very closely on these issues.

Ambassador Tobias, I am glad to see you. I enjoyed our chat outside before we came in and I really would welcome the opportunity to travel to parts of Africa with you. I am delighted that a long-time friend, Bono, is here. He is a close friend of the Leahy family. We have spent time together, each member of the family with him, and we think the world of him.

I met just briefly the lady from Uganda before and we will be seeing more of her, of Agnes Nyamayaro. And I probably—and I apologize. I have probably totally butchered the pronunciation of the name, and the poor reporter here is getting panicky at how to handle that, and I know you will do better. But I admire—as I told you privately before, I admire your courage, I really do, and you are in our thoughts and prayers.

When you think of the statistics—Ambassador, we talked about that outside. We talked about these horrible statistics—8,000 people will die of AIDS today. And as you said very rightly, the number is overwhelming, but each one has a name. And you have seen those, as has Bono and the others, as I. My wife is a registered nurse. We have been in some of these clinics. We have seen the people who are dying.

During the hour and a half of this hearing, 513 will die, 856 will become infected. That shows we have yet to confront this disease.

I support President Bush's AIDS initiative. I have been impressed with the progress you have made in the very short time since you took on this responsibility. We are allocating far more to this crisis. The momentum is positive. But the President and Secretary Thompson and others in the administration, as well as some in Congress who defend the President's budget, say we are spend-

ing as much as can be effectively used to prevent the spread of HIV and treat those who are sick.

I disagree. I think that is misinformed. In any of your 14, soon to be 15, focus countries, the medical facilities are grossly inadequate, health care workers are too few, often poorly trained, they are always underpaid. Private voluntary organizations are overwhelmed. Orphans are caring for other orphans. People are dying alone, often ostracized by their families.

There is a huge unmet need to build the capacity in those countries to fight this pandemic. That is how it is in your focus countries, which are shown in white on this chart I have got over here.

In the rest of the world, with half the HIV-infected people, we either have no programs or funding has been frozen at the fiscal year 2003 level due to a shortage of funds. So while the rate of infection soars in some non-focus countries, funding there is actually decreasing when you consider inflation and the growing number of victims and people at risk. This is a terrifying, terrifying chart.

The President has proposed to cut funding for the Global Fund to Fight AIDS, TB, and Malaria from \$547 million in 2004 to \$200 million in 2005, at a time when the Global Fund says it needs \$3.6 billion, of which our share would be \$1.2 billion. And when we ask the administration, why can we not have additional emergency funding to combat AIDS, we are told we do not need it, we cannot use it.

It reminds you a little bit of the Department of Defense, which, despite overwhelming evidence of the contrary, insists we do not need more troops in Iraq.

Mr. Tobias, we should be allocating \$28 billion next year, not \$2.8 billion. We are 20 years late, we are \$20 billion short.

Three other quick points. First, the generic drug issue, which has been the subject of a lot of press attention and has taken too long to resolve. Now that U.S. drug companies are finally interested in manufacturing fixed-dose combinations, the administration's opposition seems to have miraculously disappeared and the FDA will soon be reviewing the safety of these drugs. It makes you wonder.

Second is your emphasis on faith-based groups and abstinence. Faith-based groups have a role to play and where abstinence programs work we should support them, but we risk millions of new infections if we apply an ideological lens to prevention rather than relying on methods that have been tested and proven and that deal with the world as it really is.

Then third is your definition of "high risk" group. I heard, for example, that a 15-year-old girl in sub-Saharan Africa, where the percentage of HIV-positive females can be as high as 20 percent, could not receive condoms under your program because she is not high-risk. Yet today that girl is more likely to become infected and to die of AIDS than she is to live her life free of AIDS, more likely to have it than not. Now, I hope that girl does not have to expose herself to HIV before she can receive condoms or even information about them under your program.

Mr. Tobias, I have been trying for more than 15 years to get more funding to combat AIDS. I believe we could and should be doing more. But I hear good things, particularly from my own staff, who traveled there, and the Global Health Council, which I admire

greatly, notwithstanding the fact it is based in my home State of Vermont, I hear good things about the way you are taking on this challenge, that you are doing it with great energy and openness. I commend you for that.

PREPARED STATEMENT

Just as Senator DeWine and I work together, we all have to work together. You know, when somebody is dying of AIDS we do not ask them what their politics are. We ask what we could do to stop it. Again, you look at that map; your heart has to cry out.

Thank you.

Thank you, Mr. Chairman.

[The statement follows:]

PREPARED STATEMENT OF SENATOR PATRICK J. LEAHY

Mr. Tobias, we appreciate you being here. We all know the statistics. 8,000 people will die of AIDS today. Just during the hour and a half of this hearing, 513 will die and another 856 will become infected. To me, that shows that, so far, we have failed miserably to confront this disease.

I support President Bush's AIDS initiative, and I have been impressed with the progress you have made in the short time since you took on this responsibility. We are allocating far more than before to this crisis, and the momentum is positive. But the President, Secretary Thompson, and others in the administration, as well as some in Congress who defend the President's budget, say we are spending as much as can be effectively used to prevent the spread of HIV and treat those who are sick.

That is either misinformed, or disingenuous. In any of your 14—soon to be 15—focus countries, medical facilities are grossly inadequate, and health care workers are too few, often poorly trained, and always underpaid. Private voluntary organizations are overwhelmed. Orphans are caring for each other. People are dying alone, ostracized by their families. There is a huge, unmet need to build the capacity in those countries to fight this pandemic. That is how it is in your focus countries, which are shown in white on this chart. In the rest of the world—with half the HIV infected people—we either have no programs, or you have frozen funding at the fiscal year 2003 level due to a shortage of funds.

So while the rate of infection soars in some non-focus countries, our funding there is actually decreasing, if you consider inflation and the growing number of victims and people at risk of infection. And the President proposes to cut funding for the Global Fund to Fight AIDS, TB and Malaria from \$547 million in 2004 to \$200 million in 2005, at a time when the Global Fund says it needs \$3.6 billion, of which our share would be \$1.2 billion. Yet what we hear from the administration, when we try to get additional emergency funding to combat AIDS, is that we don't need it. We can't use it. It reminds me of the Department of Defense, which despite overwhelming evidence to the contrary, insists that we don't need more troops in Iraq.

Mr. Tobias, we should be allocating \$28 billion next year, not \$2.8 billion. We are twenty years late and \$20 billion short.

Three other quick points:

First, the generic drug issue, which has been the subject of a lot of press attention, has taken far too long to resolve. However, now that U.S. drug companies are finally interested in manufacturing fixed-dose combinations, the administration's opposition seems to have miraculously disappeared and the FDA will soon be reviewing the safety of these drugs. It makes you wonder.

Second is your emphasis on faith-based groups and abstinence. Faith-based groups have a role to play and, where abstinence programs work, we should support them. But we risk millions of new infections if we apply an ideological lens to prevention, rather than relying on methods that have been tested and proven, and that deal with the world as it really is.

Third is your definition of "high risk" group. I heard, for example, that a 15-year-old girl in sub-Saharan Africa, where the percentage of HIV-positive females can be as high as 20 percent, could not receive condoms under your program because she is not "high risk."

Yet, today that girl is more likely to become infected and to die of AIDS than she is to live her life free of AIDS. I hope that girl does not have to expose herself to HIV before she can receive condoms, or even information about condoms, under your program.

Mr. Tobias, I have been trying for more than 15 years to get more funding to combat AIDS. I believe we could and should be doing much more. But I hear good things—including from my staff and from the Global Health Council in my own state of Vermont—about the way you are taking on this challenge, with great energy and openness. I commend you for that. We need to work together.

Senator DEWINE. Mr. Ambassador, thank you very much for joining us. We do have your written statement, which will be made a part of the record, and will you please proceed.

SUMMARY STATEMENT OF HON. RANDALL L. TOBIAS

Ambassador TOBIAS. Mr. Chairman, members of the subcommittee: I am very pleased to be here to testify this morning in support of the President's budget request and to report to you on the progress in implementing the President's emergency plan for AIDS relief. I appreciate the committee's indulgence in the fact that we were scheduled to do this earlier and I was suffering from laryngitis, which as you can probably tell I am not totally over yet; and then on another occasion the President asked me to go to South Africa to represent him at the inauguration of the president.

But I am very pleased to be here today and particularly to be here with my friend Bono. It would be hard to find anybody who is working any harder on this issue than he is. As you have both said, this is a fight where we need everybody we can find to work together.

With your permission, I will submit a longer written statement for the record and I would like to make a few opening comments.

As you are aware and as you have made reference to, in his State of the Union Address last year, President Bush called for an unprecedented act of compassion to turn the tide against the ravages of HIV/AIDS with \$15 billion over 5 years, more money than has ever been committed by any nation for any international health initiative: \$5 billion directed at 100 bilateral programs, \$9 billion intended for new or expanded programs in 14—soon to be 15—focus countries; and \$1 billion intended to support our principal multilateral partner, the Global Fund.

The goals of this program are to help provide antiretroviral treatment to 2 million people in the focus countries, contribute to the prevention of 7 million new infections, and to help provide care for 10 million who are infected or affected, including the orphans and vulnerable children.

Today I am pleased to report that we have made significant progress in beginning to implement the actions that will be necessary to achieve the goals of this initiative. On February 23, a very short time after Congress appropriated fiscal year 2004 funding for the first year of the plan, I announced the first release of funds for the focus country programs, totaling \$350 million. This money is already being used in antiretroviral treatment programs, prevention programs, safe medical practices programs, and programs to provide care for orphans and vulnerable children. With just this first round of funding, an additional 50,000 people living with HIV/AIDS in the 14 focus countries will receive treatment, which will nearly double the number of people who are currently receiving treatment in sub-Saharan Africa. Prevention programs

will reach about 500,000 additional people and about 60,000 additional orphans will receive help.

For each of the focus countries, we have recently completed reviews of their annual operational plans to be addressed with the remaining 2004 appropriation. These plans represent the overall U.S. Government-supported HIV/AIDS programs in each of the focus countries.

As a result of these reviews, Mr. Chairman, we are already moving beyond this first wave of funding, and we will be providing to this committee and other congressional committees very shortly the required notification for the obligation of approximately \$300 million in the next tranche of funding from the Global AIDS Coordinator's Initiative and an additional \$200 million in funds appropriated to the Department of Health and Human Services and the U.S. Agency for International Development. That will bring to about \$850 million the funds that we will have committed to new or expanded programs since the first of the year.

While our short-term focus has been on putting funds to work in the field quickly and with accountability to ensure that those in need get help as quickly as possible, we are also working to ensure that host governments and local organizations are well prepared to fight this deadly disease. And similarly, we need to ensure that our own U.S. Government staffs in the field are properly sized in order to do this increased task that they are facing.

But this is all only the first step. In fiscal year 2005 we have requested \$1.45 billion for the Office of the AIDS Coordinator as part of the President's \$2.8 billion total request. The President's request represents a \$400 million increase over fiscal year 2004. An appropriation of \$2.8 billion will keep the emergency plan on path toward meeting the goals that have been set by the President and the Congress and is in keeping with our belief that as the emergency plan takes root and is scaled up additional resources are clearly going to be needed to effectively deliver assistance.

Mr. Chairman, in February I also submitted to Congress a comprehensive integrated 5-year strategy. This strategy is driving everything that we are doing in the Office of the Global AIDS Coordinator. We have enlisted the help of the U.S. chief of mission in each country to bring together the local country team so that everybody is working in a coordinated effort, and I am very pleased with the way that effort is working.

Within that framework, we are striving to coordinate and collaborate our efforts in order to respond as best we can to the priorities and the strategies of each of the host country governments, challenges which in many cases are different. In addition, we are increasingly coordinating our own worldwide response with those of our international partners—U.N. AIDS, the World Health Organization, the Global Fund—as well as nongovernmental and faith-based and community-based organizations and increasingly private sector companies who are stepping into the fray.

Since my confirmation 7 months ago, I have had the opportunity to visit many of the countries in which we are focusing our efforts, including South Africa, Uganda, Kenya, Botswana, Zambia, Namibia, Rwanda, Ethiopia, and Mozambique. I will be leaving in a

few days to visit Nigeria, Cote d'Ivoire, and Tanzania, and then going to Haiti and Guyana in the early summer.

Finally, Mr. Chairman, I would like to say a few words about our policy to procure antiretroviral drugs under the emergency plan, a topic that has generated a significant amount of interest. I have consistently and repeatedly expressed our intent to provide, through the emergency plan, AIDS drugs that are acquired at the lowest possible cost, whether they are brand name products, generics, or copies of brand name products, regardless of their origin or who produces them, as long as we know that they are safe and effective and of high quality.

As you know, this past Sunday Health and Human Services Secretary Thompson and I held a joint press conference in Geneva, where the World Health Assembly is currently taking place. Our purpose was to make two very important announcements that impact these issues.

First, Secretary Thompson announced an expedited process for FDA review of AIDS drugs that combine already-approved individual HIV therapies into a single dose, known as fixed-dose combination. The drugs that are approved under this expedited process will meet all FDA standards for safety, efficacy, and quality. This new FDA process will include the review of applications that may come from research-based companies that developed the individual therapies and now want to put them into fixed-dose combinations, or the applications may come from companies who are already manufacturing copies of those drugs for sale in the developing nations.

For my part, I announced in Geneva that when a new combination drug for AIDS treatment receives a positive outcome under this expedited FDA review, then the Office of the Global AIDS Coordinator will recognize that positive result as evidence of the safety and efficacy of that drug, and thus the drug will be eligible for funding by the President's emergency plan so long as the various international patent agreements and local government policies allow for their purpose.

Where it is necessary to do so, I will also use the authority that has been given to me by the Congress to waive buy-American requirements that might normally apply.

Thanks to the generosity of the American people, as well as the growing number of donor nations, the donors to the Global Fund, and other multilateral sources, the human and physical capacity to deliver AIDS treatment is being scaled up to make it possible for millions more patients to follow those who are already receiving this life-extending therapy. As infrastructure is scaled up, drug availability will also need to be scaled up to an unprecedented level in order to fuel this newly expanded set of health care systems that can deliver this treatment capacity.

It is in some ways in large part because of the President's emergency plan that the issue of drug safety needs to be addressed on an entirely new scale. With such a massive expansion of ARV treatment, the stakes have increased. If we do not apply appropriate scientific scrutiny to this vastly expanding flow of AIDS medicines, we will run the risk of causing the HIV virus to mutate and overcome specific drugs or even whole classes of drugs, and

that is why getting it right at the outset is so important and requires great care.

Our commitment from the beginning has been to move with urgency to help build the human and physical capacity that is needed to deliver this treatment and then to fund the purchase of AIDS drugs to be used in providing this treatment at the most cost-effective prices we can find, but only drugs that we can be assured are safe and effective.

Patients in Africa deserve the same assurances of safety and efficacy that we would expect for our own families here in the United States. There should not be a double standard. But how to do that has presented some serious challenges. So with our colleagues at the World Health Organization and UNAIDS and the Southern African Development Community, the U.S. Government has been carefully examining this issue and considering alternatives.

Many of the copies of the research-based AIDS drugs that are on the market today in developing countries may very well be totally safe and effective. The challenge stems in part from the fact that they have never been reviewed by any of the world's stringent regulatory authorities, and the same will likely be true of the additional copies of these drugs that will be coming to the market in the days ahead as new companies and particularly indigenous companies enter this market, something that we expect and indeed hope will happen.

Many people and organizations have noted the World Health Organization's prequalification pilot program and have urged that we simply rely on that. We have the highest respect for the World Health Organization and for its program. However, the World Health Organization is not a regulatory authority and does not represent itself as such. And in my conversations with Dr. J.W. Lee, Director General of the World Health Organization, as recently as 2 days ago, he has been very supportive, and has said so publicly, of what we are doing with this new program.

For drugs that are used in the United States, the already existing answer has been FDA approval, whether it is generic drugs or brand name drugs. Now we have a process that every drug company in the world who wants to participate in this program can submit for review to the FDA and do this very expeditiously.

Today the most limiting—

Senator DEWINE. Mr. Ambassador, if you could wrap up.

Ambassador TOBIAS. Okay.

PREPARED STATEMENT

Today the most limiting factor in providing treatment is not the drugs; it is the human and physical capacity in the health care system in Africa. But we are making progress on that and it is now time to get moving with the drugs.

I pledge that the Office of the Global AIDS Coordinator will continue to move with urgency in all that we do, and I appreciate very much the opportunity to be here today.

[The statement follows:]

PREPARED STATEMENT OF HON. RANDALL L. TOBIAS

Mr. Chairman, members of the subcommittee, I am pleased to appear before you to testify in support of the President's Budget request for fiscal year 2005 for global HIV/AIDS, and to report to you on our progress in implement the President's Emergency Plan For AIDS Relief.

In his State of the Union address last year, President Bush called for an unprecedented act of compassion to turn the tide against the ravages of HIV/AIDS.

The President committed \$15 billion over five years to address the global HIV/AIDS pandemic—more money than ever before committed by any nation for any international health care initiative:

- \$5 billion intended to provide continuing support in the approximately 100 nations where the U.S. Government currently has bilateral, regional, and volunteer HIV/AIDS programs.
- \$9 billion intended for new or expanded programs to address HIV/AIDS in 14 of those countries that are among the world's most affected—with a 15th country to be added shortly. The initial 14 countries account for approximately 50 percent of the world's HIV/AIDS infections.
- And finally, \$1 billion intended to support our principal multilateral partner in this effort, the Global Fund to Fight AIDS, Tuberculosis and Malaria, which the United States helped to found with the first contribution in May 2001.

Today, I am pleased to report that we have made significant progress in beginning to achieve the President's, the Congress's, and the American public's goal of bringing prevention, treatment, and care to millions of adults and children courageously living with HIV/AIDS and replacing despair with hope.

On February 23, just 4½ months after we launched the Office of the U.S. Global AIDS Coordinator, and less than a month after the Congress appropriated fiscal year 2004 funding for the first year of the President's Emergency Plan for AIDS Relief, I announced the first release of funds for focus country programs totaling \$350 million.

This money is being used by service providers who are bringing relief to suffering people in some of the countries hardest-hit by the HIV/AIDS pandemic to rapidly scale up programs that provide anti-retroviral treatment; prevention programs, including those targeted at youth; safe medical practices programs; and programs to provide care for orphans and vulnerable children.

These target areas were chosen because they are at the heart of the treatment, prevention and care goals of President Bush's Plan.

The programs of these specific recipients were chosen because they have existing operations among the focus countries, have a proven track record, and have the capacity to rapidly scale up their operations and begin having an immediate impact.

Our intent has been to move as quickly as possible to bring immediate relief to those who are suffering the devastation of HIV/AIDS.

By initially concentrating on scaling up existing programs that have proven experience and measurable track records, that's exactly what we have been able to do.

With just this first round of funds, an additional 50,000 people living with HIV/AIDS in the 14 focus countries will begin to receive anti-retroviral treatment, which will nearly double the number of people who are currently receiving treatment in all of sub-Saharan Africa. Today, activities have been approved for anti-retroviral treatment in Kenya, Nigeria, and Zambia, and patients are receiving treatment in South Africa and Uganda because of the Emergency Plan.

In addition, prevention through abstinence messages will reach about 500,000 additional young people in the Plan's 14 focus countries in Africa and the Caribbean through programs like World Relief and the American Red Cross's Together We Can.

The first release of funding from the President's Emergency Plan will also provide resources to assist in the care of about 60,000 additional orphans in the Plan's 14 focus countries in Africa and the Caribbean. These care services will include providing critical social services, scaling up basic community-care packages of preventive treatment and safe water, as well as HIV/AIDS prevention education.

U.S. Government staff recently completed reviews of each of the focus country's annual operational plans to be addressed with the remaining fiscal year 2004 appropriation. These plans represent the overall U.S. Government-supported HIV/AIDS prevention, treatment, and care activities in each focus country.

As a result of these reviews, Mr. Chairman, we will be providing to this Committee and other congressional committees the required notification for the obligation of approximately \$300 million in the next tranche of funding from the Global HIV/AIDS Initiative account. In addition to that \$300 million, another \$200 million of funds appropriated to the U.S. Department of Health and Human Services and

the U.S. Agency for International Development will be put to work in the field, bringing to approximately \$850 million the funds already committed to new or expanded programs since the first of the year.

As we make additional awards, the numbers of persons receiving treatment and care will increase substantially. I also expect our efforts to strengthen and expand safe blood transfusion and safe medical injection programs, as well as our efforts to strengthen human and organizational capacity through healthcare twinning and volunteers. And I also expect to place an additional focus on attracting new partners, including more faith-based and community-based organizations that can bring expanded capacity and innovative new thinking to this effort.

Mr. Chairman, as I mentioned, our short-term focus has been putting funding to work in the field quickly and with accountability to ensure that those in need get help as quickly as possible. In addition to these important ideals and the achievement of our treatment, prevention and care goals, in the long term we are focused on strengthening indigenous capacity. We need to ensure that host governments and local organizations are well prepared to fight this deadly disease. Similarly, we need to ensure that our own U.S. Government staff in the field is properly sized to work closely with host governments over the next four years in accomplishing the goals of the Emergency Plan.

But this is only the first step. In fiscal year 2005 we requested \$1.45 billion for the Office of the Coordinator as part of the President's \$2.8 billion request. With these funds we will continue to expand access to care, treatment and prevention and also take the next steps to build the necessary U.S. Government and host country capacity needed for this Initiative. To this end, we are working with HHS and USAID now to create a vehicle to help provide the necessary technical assistance to small indigenous non-governmental and faith-based organizations to become a more integral part of the solution to fighting HIV/AIDS in their country. We are also working with USAID, HHS and other relevant agencies to determine a long-term staffing plan.

As I mentioned, the President's total Emergency Plan request for fiscal year 2005 is for \$2.8 billion, a \$400 million increase over the fiscal year 2004 appropriation—the first year of the Emergency Plan. This request is in keeping with our belief that as the Emergency Plan takes root and is scaled up, additional resources will be needed to effectively deliver assistance. An appropriation of \$2.8 billion will keep the Emergency Plan on the path toward meeting the prevention, treatment and care goals set by the President and the Congress. The appropriation will also maintain U.S. leadership in the Global Fund to Fight AIDS, Tuberculosis and Malaria.

Mr. Chairman, in addition to announcing the first round of funding and preparing to obligate the remaining fiscal year 2004 funds, I also submitted to this Committee and other appropriate Congressional committees in February a comprehensive, integrated, five-year strategy for the President's Emergency Plan for AIDS Relief.

This Strategic Plan is guiding our efforts to deploy our resources to maximum effect:

- We are concentrating on prevention, treatment and care, the focus of the President's Emergency Plan.
- In the 15 focus countries, over the five years of the Emergency Plan:
 - We will help to provide anti-retroviral treatment for two million people;
 - We will contribute to the prevention of 7 million new HIV infections; and,
 - We will help provide care to 10 million people who are infected or affected by the disease in the focus countries, including orphans and vulnerable children.
- We are not starting from scratch. Rather, we are capitalizing on existing core strengths of the U.S. Government, including:
 - Established funding and disbursement mechanisms;
 - Two decades of expertise fighting HIV/AIDS in the United States and worldwide;
 - Field presence and strong relationships with host governments in over 100 countries; and,
 - Well-developed partnerships with non-governmental, faith-based and international organizations that can deliver HIV/AIDS programs.

Starting with this foundation, we are implementing a new leadership model for those existing capabilities—a model that brings together, under the direction of the U.S. Global AIDS Coordinator, all of the programs and personnel of all agencies and departments of the U.S. Government engaged in this effort. This leadership model has been translated to the field, where the U.S. Chief of Mission in each country is leading an interagency process on-the-ground. In addition to the work that has been done to develop the programs for fiscal year 2004 that we are or soon will be funding, in early fall each country team will submit to my office a unified five-year

overarching strategic plan to define how the President's prevention, care and treatment goals will be achieved in that country.

The Emergency Plan is built on four cornerstones, which guide my office:

1. Rapidly expanding integrated prevention, care, and treatment in the focus countries by building on existing successful programs that are consistent with the principles of the Plan—as we have already begun with the \$350 million announced in February.

2. Identifying new partners, including faith-based and community-based organizations, and building indigenous capacity to sustain a long-term and broad local response.

3. Encouraging bold national leadership around the world, and engendering the creation of sound enabling policy environments in every country for combating HIV/AIDS and mitigating its consequences.

4. Implementing strong strategic information systems that will provide vital feedback and input to direct our continued learning and identification of best practices.

Within that framework, we are striving to coordinate and collaborate our efforts in order to respond to local needs and to be consistent with host government strategies and priorities.

In addition, we intend to amplify our own worldwide response to HIV/AIDS by working with international partners, such as UNAIDS, the World Health Organization, and the Global Fund, as well as through non-governmental organizations, faith- and community-based organizations, private-sector companies, and others who can assist us in engendering new leadership and resources to fight HIV/AIDS.

Since my confirmation seven months ago, I have had the opportunity to visit many of the countries in which we are focusing our efforts, including South Africa, Uganda, Kenya, Botswana, Zambia, Namibia, Rwanda, Ethiopia, and Mozambique. I'll be leaving in a few days for a visit that will include Nigeria, Cote d'Ivoire and Tanzania.

In these visits, I have witnessed how these countries have responded, in whatever way they can, to fellow community members in need. As we embark on this effort, it is inspiring to observe the remarkable self-help already under way in fighting HIV/AIDS by some of the most under-resourced communities in the world. With our support, we hope to broaden, deepen and sustain their efforts to combat the devastation of HIV/AIDS.

That is why getting the first wave of funding released quickly after the appropriation was so critical, and I appreciate the Congress's assistance in ensuring that was able to happen. I again seek your support in ensuring that we are able to quickly move the additional resources about to be sent up so we can respond with the urgency these individuals in need require.

Finally, Mr. Chairman, I would like to say a few words about our policy to procure anti-retroviral drugs under the Emergency Plan—a topic that has generated a significant amount of interest.

I have consistently and repeatedly expressed our intent to provide, through the Emergency Plan, AIDS drugs that are acquired at the lowest possible cost, regardless of origin or who produces them, as long as we know they are safe, effective, and of high quality. These drugs may include brand name products, generics, or copies of brand name products.

To define the terms here, when you or I go to our neighborhood pharmacy and have a prescription filled with a generic drug, we do so with the confidence that we are being given a drug that has undergone regulatory review to ensure that it is comparable to the version manufactured by the research-based company that originally created it, but no longer has the patent rights to the product. It is the same drug in dosage form, strength, route of administration, quality, performance characteristics, and intended use. Drugs that have not gone through such a process are more accurately described as copy drugs rather than generics, as they are sometimes called.

This past Sunday, Health and Human Services Secretary Tommy Thompson and I held a joint press conference in Geneva where the World Health Assembly is currently taking place. Our purpose was to make two very important announcements that impact on these issues.

First, Secretary Thompson announced an expedited process for FDA review of applications for HIV/AIDS drug products that combine already-approved individual HIV/AIDS therapies into a single dosage. These combined therapies are known as fixed dose combinations or FDCs. Drugs that are approved by FDA under this process will meet all FDA standards for drug safety, efficacy, and quality.

This new FDA process will include the review of applications from the research-based companies that developed the already-approved individual therapies and want to put them into fixed dose combinations, or from companies who are manufacturing

copies of those drugs for sale in developing nations. There are no true generic versions of these AIDS drugs because they all remain under intellectual property protection here in the United States.

For my part, I announced that when a new combination drug for AIDS treatment receives a positive outcome under this expedited FDA review, the Office of the Global AIDS Coordinator will recognize that result as evidence of the safety and efficacy of that drug. Thus the drug will be eligible to be a candidate for funding by the President's Emergency Plan, so long as international patent agreements and local government policies allow their purchase. Where it is necessary and appropriate to do so, I will also use my authority to waive the "Buy American" requirements that might normally apply.

The issue of determining the safety and efficacy of the copy drugs is, in some ways, a positive problem to have. Many have argued over the years that bringing antiretroviral therapy to places like Africa on a large scale could never happen—that the problems were too complex. Well they were wrong. It is happening now—today.

Because of the President's Emergency Plan For AIDS Relief, and with the partnerships between this initiative and those who are directly delivering treatment—the NGO's and faith-based organizations, the medical care-givers and the health-care delivery facilities of the governments of these nations themselves, just a few short months after launching the President's Emergency Plan, we have already increased by thousands the numbers of patients suffering from HIV/AIDS who are now on life-extending ARV treatment.

Thanks to the generosity of the American people as well as a growing number of donor nations, the donors to the Global Fund and other multi-lateral sources, companies in the private sector, private foundations and others, as the human and physical capacity to deliver AIDS treatment is scaled up to make it possible, millions more patients will follow those who are already receiving this life extending therapy.

Drug availability will also need to be scaled up to an unprecedented level in order to fuel this newly expanded treatment capacity. It is in large part because the President's Emergency Plan for AIDS Relief has made such a dramatic commitment to making drug treatment available that issues of safety need to be addressed on an entirely new scale. With such a massive expansion of ARV treatment, the stakes have increased.

If we don't apply appropriate scientific scrutiny to this vastly expanded flow of AIDS medicines, we will run the risk of causing the HIV virus to mutate and overcome specific drugs or even whole classes of drugs. That could render our current drugs useless—and, incredibly, it could leave Africa even worse off than it is today. That's why getting this right at the outset is so important and requires great care.

Our commitment, from the beginning, has been to move with urgency to help build the human and physical capacity that is needed to deliver this treatment, and then to fund the purchase of AIDS drugs to be used in providing this treatment, at the most cost effective prices we can find—but only drugs that we can be assured are safe and effective. Patients in Africa deserve the same assurances of safety and efficacy that we expect for our own families here in the United States. There should not be a double standard. But how to do that has presented some serious challenges. With our colleagues at the WHO, UNAIDS, the Southern African Development Community, and many others, the U.S. Government has been carefully examining this issue—and considering alternatives.

Many of the copies of the research-based AIDS drugs that are on the market today in developing countries may well be safe and effective. The challenge stems in part from the fact that they have never been reviewed by any of the world's stringent regulatory authorities. And the same will likely be true of the additional copies of those drugs that will surely be coming on the market in the days to come, as new indigenous companies enter this market—something we expect and hope will happen.

Many people and organizations have noted the World Health Organization's prequalification pilot program and have urged that we simply rely on it. We have the highest respect for the WHO and its program. However, the WHO is not a regulatory authority and does not represent itself as such.

For drugs that are used in the United States, the already existing answer to ensuring safety and efficacy is simple: both research-based companies and generic companies submit their products to the U.S. Food and Drug Administration for review and approval. What FDA has announced is a process that will not only make it possible, but relatively fast and easy, for every manufacturer to now submit their AIDS drugs to that same scrutiny, including those that will only be made available in developing countries. If those drugs meet the appropriate standards—as we hope

many or all will do—they can then be approved for potential funding by the President's Emergency Plan.

I hope that FDA will receive applications as soon as possible from many companies that will want their drugs to be candidates for U.S. funding for use in the treatment programs of the President's Emergency Plan. If this process enables us to get safe and effective drugs at lower prices than we do now, that would indeed be a great success.

Today the most limiting factor in providing treatment is not drugs—it is the human and physical capacity in the health care systems of Africa. The continent is desperately short of health care infrastructure and health care workers. Both are needed in order to deliver treatment broadly and effectively. We find that African leaders and African AIDS advocates are quite focused on addressing this limitation—because they know that all the drugs in the world won't do any good if they're stuck in warehouses with no place to go to actually be part of the delivery of treatment to those in need.

But as we successfully attack that issue and Africa's capacity to deliver drug treatment grows, drug availability will become an increasingly significant constraint on treatment. We can't let that happen.

For our part, I pledge that the Office of the Global AIDS Coordinator will continue to move with urgency in all that we do. President Bush has made clear to me that this is an emergency at the top of the list of America's priorities. We will act accordingly.

Mr. Chairman, I am grateful for this Committee's resolve to defeat the HIV/AIDS pandemic. Your leadership and support has facilitated the speed with which we are responding to people in need, and that commitment will ensure our success—success that will be measured in lives saved, families held intact, and nations again moving forward without the shadow of this terrible pandemic.

I would be pleased to respond to any questions you may have.

Senator DEWINE. Mr. Ambassador, let me turn to the prevention of mother-to-child transmission issue. Fiscal year 2004 is actually the last year of this program. My understanding is that your plan is that beginning with fiscal year 2005 the budget does not provide any specific line item for this and that this program would be incorporated actually under your office.

I wonder if you could tell us what you are anticipating for this program, how much you are looking at spending under your office, and what your plans are for the non-initiative countries for this program?

Ambassador TOBIAS. Senator, the prevention of mother-to-child transmission program has been very important, not only in treatment terms but also one could argue in orphan terms. I think you could make the case that the most effective orphan program we can have is keeping the mothers alive so that we do not have the orphans. The program to prevent mother-to-child transmission has been very effective. It is relatively inexpensive and it is a program that we will expand, not only in the countries in the program where it exists but well beyond that as we can.

We are now going to something that is generally referred to as the mother-to-child transmission plus program, in that the mother-to-child transmission program per se really focused on protecting the health of the child and ensuring that when the baby was born the odds were improved that the baby would be infection-free. But what about the mother, what about the father, what about the siblings that are in that family? So the mother-to-child transmission plus program will begin to address those, too.

This program, as you know, was started in the countries that became the focus countries. I think it gave us an important jump start on getting the emergency plan implemented. I would hope that we can find ways to take the lessons that we are learning in

the focus countries and begin to expand those lessons into the so-called non-focus countries as we go forward and as funding permits.

Senator DEWINE. The plus program is certainly a wonderful idea and I think we all understand how important it is to keep the mother alive and keep the mother there for the children. I guess the concern would be that that prevents us—that focus might—you know, these are tough choices—might prevent us from moving forward into other communities and to other areas and expanding the mother-to-child program.

What are the tradeoffs here? Let us be honest. What are we talking about?

Ambassador TOBIAS. Well, you are exactly right with respect to the issue of tradeoffs. There are tradeoffs virtually everywhere we look.

Senator DEWINE. I mean, the mother-to-child program can be a fairly cheap program if you have got the infrastructure to implement it. It certainly is cheap as far as what the drugs cost if you can get the infrastructure going.

Ambassador TOBIAS. I certainly do not anticipate that we are talking about an either-or situation here. I think that we need to, as you suggest, expand the mother-to-child transmission program, but with the building of increased infrastructure and the capabilities that we are putting in place I also believe that we can expand that into the mother-to-child plus program also.

Much of what we do will be driven by the policies that are established by the health officials and the government leaders in each of the countries in which we operate, and we need to pay close attention to that.

Senator DEWINE. Let me move to another area because I have one last question and my time is almost up. Let me move to the pediatric treatment, which I touched on in my opening statement. How does the President's 5-year strategy incorporate the special needs of children who are infected with HIV and require HIV treatment? What is the administration going to do to ensure that all HIV/AIDS drugs are available for pediatric use? And what is the administration going to do to ensure that both pediatric professionals and other HIV/AIDS workers have the necessary information and training to treat children infected with HIV/AIDS?

Ambassador TOBIAS. I think you are very correct, Senator, that not only in this field but in other fields the amount of pediatric-specific research that has been done has been too little, and we clearly need more in this field. I will rely on the medical experts and the technical experts as to exactly how we need to address this, but we do need to expand the care to HIV-infected young people.

But again, the best answer to that is the mother-to-child transmission program and things like that to keep that infection from going—

Senator DEWINE. No doubt about it, it is the most cost-effective and we can save the most lives with the mother-to-child. But still, every country I visited—and I visited a number of them—we have got kids out there who are dying and there are kids out there who

could be saved if we could get the treatment to them, and we do not want to forget them.

Senator Leahy.

Senator LEAHY. Thank you, Mr. Chairman.

As you may have gathered by some of the demonstrators here this morning, there is some concern on the question of generic drugs. For months you had said: "There is no process, no principles, no standards in place today," to assure the safety of generic fixed-dose combinations manufactured overseas. Now, many health experts and the World Health Organization disagreed with you.

Now we have a new review process. How do you answer the fact that it appeared the review process came up after U.S. companies were interested in manufacturing their own fixed-dose combination drugs? And even then, how long is it going to take for this review process? I am just wondering if we have just one more unnecessary obstacle to getting these drugs out to the people who need them desperately.

Ambassador TOBIAS. Well, Senator, first let me say that the World Health Organization does not present their prequalification program to be the equivalent of regulatory review. I would simply refer to the statement that has been released by Dr. J.W. Lee, the head of the World Health Organization, in total support of the program that we are putting in place to review these drugs.

Senator LEAHY. When will we have the drugs out there?

Ambassador TOBIAS. The FDA tells me that if, for example, companies are applying today, which they could, that in some cases approval could be received in as little as 2 weeks. In some cases it could be 6 weeks or so, depending on the data. Then it will depend on the programs in individual countries. But we will be certainly ready to go.

Senator LEAHY. Would we have gone to a generic fixed-dose combination if American drug companies had not shown an interest in producing it themselves?

Ambassador TOBIAS. Well, the announcement that I have read in the media, as you have, from the American companies, came after we announced this program, which we have been working on with the FDA for some time. I have said on a number of occasions that we are totally in favor of fixed-dose combinations. The issue has never been whether fixed-dose combinations are good or bad. I do not think there is any question with anybody that they are good because they make it easier for doctors to administer the program and patients to adhere.

Senator LEAHY. I am just trying to see what this is. This is today's New York Times and, for what it is worth: "A WHO official familiar with both his agency's approval process and the outlines of the proposed American one said, 'Although the United States has not exactly been in love with our prequalification process, they are now going to do exactly the same. If they want to create a parallel structure and do a good job, that is fine.'"

Let me ask you this—and I will put the whole article in the record. Over the next 5 years, you say you hope to prevent 7 million new HIV/AIDS infections. We all agree that would be a great achievement. There are 5 million new ones each year. So even if

you succeed, there will be at least 18 million new infected people by the end of 5 years, 2.5 times the number we have prevented.

I raise this because in my opening statement you remember I mentioned the issue of absorptive capacity, what can we do. How did you come up with the number \$2.8 billion for fiscal year 2005? Could we not be doing a lot more? Because it seems to me we are in some ways chasing after the train. We are not keeping up with even the rate of infection, to say nothing about helping those who are direly in need.

I am told by so many that we have the capacity, if the money was there, we have the capacity to do more. We have private organizations, private groups. The Gates Foundation did a lot more on this than the United States was willing to initially.

[The information follows:]

[From the New York Times, Tuesday, May 19, 2004]

VIEWS MIXED ON U.S. SHIFT ON DRUGS FOR AIDS

(By Donald G. McNeil Jr.)

AIDS activists and doctors who treat patients in poor countries greeted the Bush administration's shift in its policy on procuring AIDS drugs with mixed reviews yesterday.

Many were delighted that the administration had decided to buy anti-AIDS cocktails that combine three drugs in one pill, and that it for the first time was willing to consider buying drugs from low-cost generic manufacturers, who are now the only companies making 3-in-1 pills.

"I think it's fabulous," said Dr. Merle Sande, who treats 4,000 AIDS patients in Uganda, most of whom cannot afford drugs. Most of those who can are on Triomune, a 3-in-1 pill from Cipla Ltd., an Indian company. Three-in-one drugs, he said, "are exactly what we need out there."

At the same time, some activists expressed frustration that the White House had set up a new approval process overseen by the United States Food and Drug Administration when one overseen by the World Health Organization already existed.

"This just another roadblock," said William Haddad, an American generic manufacturer who now consults for Cipla. "The W.H.O. process was a pain in the neck—it took us two years to get Triomune approved. Why do we have to bend over and let them kick us again?"

Henry A. Waxman, a Democratic Los-Angeles area congressman who has harshly criticized the Bush administration's previous refusal to spend money on generic drugs said yesterday that he was "disappointed that the plan does not involve cooperation with the World Health Organization."

"We need to see the fine print before we can tell if the new process will actually improve access to these affordable, effective drugs," he said.

Even though the administration indicated that it would waive the usual \$500,000 fee for approving a drug and will let companies submit published data instead of starting new clinical trials, any new approval process involves reams of paperwork, legal expenses and time, critics said.

The World Health Organization had no official reaction yet to the decision, a spokeswoman said.

But a W.H.O. official familiar with both his agency's approval process and the outlines of the proposed American one, speaking on condition of anonymity, shrugged off the problem. "Although the United States has not exactly been in love with our prequalification process, they are now going to do exactly the same," he said. "If they want to create a parallel structure and do a good job, that's fine."

The official questioned how Tommy G. Thompson, the secretary of health and human services, could promise to approve new drugs in as little as two to six weeks unless it simply accepted all the data submitted to the W.H.O. "For us, even if everything is perfect, it takes a minimum of three months," he said.

Dr. Mark Goldenberger, director of the Food and Drug Administration's office that evaluates drugs for infectious diseases, said that "two weeks would be at the extreme short end" and would probably apply only to something like putting three already-approved drugs in one plastic blister pack, because all the agency would look at was the packaging.

Asked if the F.D.A. would accept information gathered by W.H.O. inspectors, Jason Brodsky, an agency spokesman, said that there was not any agreement allowing it, "but we would be willing to consider any information that we got from other countries in deciding whether or not we'd inspect."

On Sunday, as health ministers from around the world were gathering in Geneva for their annual meeting, the Bush administration made a surprise announcement that it would speed up its approval process for AIDS drugs to be bought for very poor countries and would consider generic drugs, 3-in-1 pills and letting different companies package their drugs together. The administration had been expected to face heavy criticism at the weeklong meeting for its previous reluctance to approve generic AIDS drugs.

Some companies appeared to have been told of the administration's announcement in advance. Merck, Bristol-Myers Squibb and Gilead Sciences immediately issued a joint statement saying they planned to develop a 3-in-1 pill. GlaxoSmithKline and Boehringer Ingelheim said they were discussing packaging three of their drugs together.

"Obviously, they had inside information," complained Dr. Paul Zeitz, director of the Global AIDS Alliance, which pushes for cheaper AIDS drugs for the third world. "That calls into question the honest broker role of the U.S. government."

Ambassador TOBIAS. Senator, I think there is no question that the magnitude, the broad magnitude of this problem, goes well beyond the resources and the focus of the President's emergency plan. I do not think the emergency plan was intended to attack the entire problem. We need to get more resources and more participation from other people in the world.

In 2003 the contributions of the U.S. Government for international HIV/AIDS totaled more than the rest of the world's governments combined. We are on a path so that in 2004 our contributions may well be close to twice as much as the rest of the world combined. So we are doing a lot, but the rest of the world needs to do more.

I think the issue is not where do these dollars fit in with the magnitude of the problem. It really is can we efficiently and effectively absorb the resources that we are bringing to bear and use them as well as possible, and I think reasonable people can disagree. But we are moving pretty quickly, and I think we will know more in the months ahead.

Senator LEAHY. My time is up, but I wonder if the chairman would allow me one more question here. And we should carry on that conversation.

Ambassador TOBIAS. Yes, sir.

Senator LEAHY. Because I believe we could be doing a lot more than we are, and I believe we have set some artificial barriers to doing more.

But I looked at an editorial today saying that the administration feels condoms are not effective in preventing the spread of HIV in the general population. I mentioned in my opening statement the 15-year-old African girl. "On average, adolescents become sexually active at 16 to 17 years of age, some even younger. In some African countries, infections among women are rising fastest among those who are married. Sexual abuse and coercion within marriage is widespread."

I mean, how long do you have to wait to receive accurate information about the importance and effectiveness of condoms in preventing AIDS? You have taken—I understand this was taken off, this information was taken off the CDC and USAID web sites. How do we answer these questions?

They say, in the editorial, it says: "Randall Tobias, its AIDS Coordinator, has said numerous times that condoms are not effective at preventing the spread of AIDS in the general population." The editorial goes on to say: "Mr. Tobias is wrong."

Here is your chance to respond.

Ambassador TOBIAS. Senator, here is the report in my hand from the London School—

Senator LEAHY. School of Hygiene and Tropical Medicine.

Ambassador TOBIAS [continuing]. The London School of Hygiene and Tropical Medicine, which allegedly does not exist. And it says exactly what I have said before, that in their study less than 7 percent of women used a condom in their last sex act with their main partner; less than 50 percent of women with casual partners used a condom.

There is a new study from—

Senator LEAHY. Less than 50 percent do; does that mean that, say, 40 percent or so do?

Ambassador TOBIAS. Well, this is again a study in a broad-based population. But the point is—and let me make just one more reference. There is a new UNAIDS study out that was peer-reviewed by the Population Council's peer review process, and just one quote from that: "There are no clear examples that have emerged yet of a country that has turned back a generalized epidemic primarily by means of condom promotion."

Senator LEAHY. Primarily, primarily.

Ambassador TOBIAS. Yes.

Senator LEAHY. Do you believe they should be withheld—

Ambassador TOBIAS. No.

Senator LEAHY [continuing]. From 15- or 16-year-olds?

Ambassador TOBIAS. No, absolutely not. Our program is A, B, C.

Senator LEAHY. Absolutely not. A 15-year-old, it would not be withheld?

Ambassador TOBIAS. The person that you described earlier, as I understood your description, would be someone that ought to have condoms available. I was in an area in northern Kenya recently where the incidence rate in 15- to 24-year-old girls is 24 percent and it is 4 percent in boys. But the evidence is that is not going to solve the problem, and we need to do a number of other things. That is why we are putting a lot of emphasis on the messages that Uganda has proven can be effective by getting young people to understand that if they delay the age at which they become sexually active and then if people who become sexually active reduce their number of partners, hopefully to one, those are the two factors that have been demonstrated to make a big difference.

But condoms are an important part of our program.

Senator LEAHY. It would also help if that woman who reduces it to one, if her partner had reduced it to that one, too. Often that is not the case.

Ambassador TOBIAS. Well, and that is where testing is so critically important. You are absolutely right.

Senator LEAHY. Thank you, Mr. Chairman.

OPENING STATEMENT OF SENATOR MITCH MC CONNELL

Senator McCONNELL [presiding]. Thank you, Senator Leahy.

The President's HIV/AIDS initiative is focused on 14 countries in Africa and the Caribbean. Congress added an additional country in the fiscal year 2004 Foreign Operations bill. Have you identified the fifteenth focus country and what criteria are you using to select that country?

Ambassador TOBIAS. Senator, we have not identified the country yet. I have gotten input from a variety of sources throughout the government and beyond. We identified 39 candidate countries that anybody could think of. We put together a list of criteria looking at the infection rate, the health care system, the national leadership, which is a critically important issue, and how helpful the leadership could be and so forth.

We are in the process of getting that down to a very short list and I am hoping that in a relatively short time we will be in a position to make that selection.

Senator MCCONNELL. Some have expressed concern that the administration is actually shortchanging countries that are not on the focus list of 15 and that more should be done to address rising infection rates in certain non-focus countries. Do you have any response to those criticisms? And are non-focus countries targeted for increases in bilateral assistance next year?

Ambassador TOBIAS. Senator, one of the important principles of the President's program is focus. It is to try to keep this from being an inch wide—or an inch deep and a thousand miles wide and not really being able to make an impact.

But we also need to recognize that this is not a disease that respects political boundaries. So we need to do what we can in the so-called non-focus countries. I am looking for some ways to shift at least some amount of resources into some of the non-focus countries that are being hit the hardest. But I think it is very important that we not lose sight of the focus aspect of this program, because the focus countries really represent 50 percent of the infections in the world and I think it is very important that we make a major impact there.

Senator MCCONNELL. I agree.

The fiscal 2005 budget request for a contribution to the Global Fund to Fight AIDS, Tuberculosis, and Malaria is \$200 million. In the fiscal year 2004 Foreign Operations bill Congress provided not less than \$400 million as a contribution to the Fund, which was \$200 million above the request.

Has the congressionally mandated increase leveraged additional contributions from other donors? How can we get, for example, donors like Russia—\$20 million, Saudi Arabia—\$10 million, and Singapore—\$1 million—to contribute more?

Ambassador TOBIAS. Well, I think there are a number of ways we can do that. One of them is leadership. I have asked the President to mention this subject every time he has the opportunity. The Secretary of State is doing the same thing. I think the work that Bono is doing to draw attention to this and encourage the rest of the world to step up to this is extremely important, because we need to make this a program that gets broad support from all governments.

Senator MCCONNELL. Do you think Congress should provide \$400 million for the Global Fund next year? And if we did that, do you

anticipate U.S. contributions exceeding 33 percent of the total amount contributed to the fund?

Ambassador TOBIAS. Mr. Chairman, the amount that the President has requested in his budget of \$200 million is consistent with the original \$15 billion proposal. This is one of those arguable tradeoff areas in the sense that the incremental difference between what the administration requested and what was appropriated to the Global Fund is money that might have been available for us to use to focus on the non-focus countries.

So it is a matter of the tradeoffs of how we want to do that. The Global Fund is a very important part of our overall strategy.

Senator MCCONNELL. Is it being effective, yielding results out in the field?

Ambassador TOBIAS. Well, it is new. It is only 2½ years old. They are experiencing the kinds of growing pains that would be expected. We are putting money into technical support in countries where the Global Fund is issuing grants in order to try to help those countries, first of all, be more effective in writing their grant proposals to the Global Fund, and then in utilizing and implementing the resources that come from the Global Fund.

PREPARED STATEMENT

Senator MCCONNELL. I have great hope for the Global Fund over time. But again, it is relatively new and it is just getting started.

Thank you, Mr. Ambassador.

[The statement follows:]

PREPARED STATEMENT OF SENATOR MITCH MCCONNELL

Today, HIV/AIDS is recognized as a significant transnational crisis that poses an immediate and growing threat to social, economic and political stability across the globe. While it may be expedient to frame the pandemic in geopolitical terms, it is far more difficult—indeed horrific—to comprehend the devastation of the virus in personal, human terms.

The statistics are staggering. As many as 46 million people live with HIV/AIDS today, and an estimated 20 million have already perished from complications of the virus. Last year alone, 5 million people became newly infected, and 3 million died from AIDS complications.

This viral holocaust creates widows and orphans and destroys entire families. It is especially brutal to youth, and saps the hope and promise of future generations. If left unchecked in developing countries, it is conceivable that HIV/AIDS will destroy entire societies, economies and political systems.

Under President Bush's leadership, America has significantly increased its contributions to combating this disease. Over a five year period, we will contribute a total of \$15 billion to HIV/AIDS programs and activities. Fifteen countries, primarily in Africa and the Caribbean, are the main focus of this initiative, although funding will continue to some 100 countries where we have ongoing programs, and to the Global Fund to Fight AIDS, Tuberculosis and Malaria.

There are no shortages to the challenges in successfully managing this disease. Some argue that we—and other nations—should spend more on HIV/AIDS, and that we shortchange the cause by not providing the \$3 billion authorized by Congress in the AIDS bill.

Perhaps America should spend more, but that will ultimately be determined by fiscal constraints. I would point out, however, that last year's budget request for HIV/AIDS programs exceeded the total amount provided from fiscal years 1993 through 2001. Further, the President's plan gradually increases spending over the five year period so that beginning in fiscal year 2006, the budget request exceeds \$3 billion and tops nearly \$4 billion in fiscal year 2008.

Funding alone is not enough. To stem the tide of HIV/AIDS, nations must have committed leadership, the most basic health care delivery systems, and the capacity

to absorb substantial assistance targeted toward the health and welfare of all people—regardless of ethnic, tribal, political, gender, or religious affiliation.

It will be an uphill battle. Of the 12 focus countries included in the Transparency International Corruption Perception Index 2003, only one—Botswana—is above a half-way mark of five. Nine countries rated below a three. In 2003, Freedom House scored only four focus countries as “free”—seven were rated “partly free” and three “not free”.

“A business as usual” approach by focus countries will only translate into more lost lives and greater tragedy for millions of people. Many stand ready to help, including such faith-based organization as Lott-Carey International (LCI). I strongly encourage the Coordinator’s office to use the experience and indigenous contacts that LCI and other groups bring to this effort.

Let me close with brief comments on Burma and South Africa—countries which represent the range of freedom in the developing world. In Burma, a military junta daily abuses and denies the rights of its citizenry, including access to even the most basic health care and medicines. While we may not accurately know the extent of the HIV/AIDS infection rate in Burma, we do know that the pandemic cannot be addressed by an illegitimate regime that places the welfare of the people far below the acquisition of Russian MiGs, nuclear reactors and money laundering.

In South Africa, a country whose journey toward democracy has been nothing but inspirational, the lack of political will by the Mbeki government to address the HIV/AIDS pandemic head-on has wasted precious time in stemming the tide. South Africa’s heroes are the health care workers at the grassroots level; the current government must be willing to partner with them—and available science—to combat the disease.

It is my hope that in the future President Mbeki will be as vigilant on this issue as both our witnesses here today.

Senator McCONNELL. Senator Durbin.

OPENING STATEMENT OF SENATOR RICHARD J. DURBIN

Senator DURBIN. Mr. Ambassador, thank you very much.

Sometimes I get the impression that different rooms on Capitol Hill are really living in different worlds. Last week we entertained people from the administration who, having told us in February they would need no additional funds for the war in Iraq, had a different point of view and came to tell us that they needed \$25 billion and then, Assistant Secretary Wolfowitz said, maybe \$50 billion on an emergency basis.

The reasoning was hard to argue with. They said the war is not going well, our national interests are at stake, we cannot turn our back on our commitments, and we cannot turn our backs on people whose lives are at stake as well.

I might say the same thing about the global AIDS epidemic. That war is not going well either, our national interests are at stake, we cannot turn our back on our commitments, there are people who have their lives at stake.

As I look at the administration, I thought that the President’s announcement a little over a year ago of a \$15 billion commitment was historic, receiving broad bipartisan support. His first budget request, the first of the 5 years was \$2 billion. With the kind efforts of Senator DeWine and my colleagues, we raised that to \$2.4 billion on the floor.

Then came this year’s budget request of \$2.8 billion, still short of the mark of keeping up with the \$15 billion commitment. With Senator Lugar and Senator DeWine and others, we brought this up to \$3.3 billion in the budget resolution.

But, going to a point that Chairman McConnell raised, how can we rationalize or justify such a dramatic decrease in our commitment to the Global Fund? You received a letter from Dr. Feicham

on March 25 of this year and he made it clear that the amount that we are talking about appropriating for the Global Fund is dramatically inadequate. For this effort to reach its goal and to save lives across America, he believes \$1.2 billion is needed from the United States.

I think good evidence is there to support that position. Why do you feel that, instead of increasing our commitment to the war on AIDS, that we can start retrenching and pulling back in this next fiscal year?

Ambassador TOBIAS. Well, Senator, the budget request for 2005 is in fact the same amount that the administration requested in the previous year and that is reflected in the billion dollar component of the first \$15 billion request. I am very supportive of the Global Fund, but I am also very supportive of the President's emergency plan. I want to be sure that we are not making tradeoffs that get in the way of our doing the things that we are demonstrating we can do of getting the money out and getting it to work very quickly.

Dr. Feachem is talking about the broad need out there. I think we need to focus on the money we are getting out the door today and next month and in the next year.

Senator DURBIN. So do you think he is overstating his need for next year?

Ambassador TOBIAS. No, I do not think he is overstating the need, but he may be overstating the ability to utilize those funds that quickly. But again, I want to make clear that the Global Fund is certainly a very important aspect of our overall strategy.

Senator DURBIN. I would say, Ambassador, that that is a fundamental error of this administration. I believe it is important for us to maintain our bilateral commitment to the 14 nations, ultimately 15. But the Global Fund is serving a large part of the world that we are not addressing with bilateral assistance. I have seen that part of the world—India for example, desperate to see their Global Fund projects not only initially authorized, but carried on. When we fall so far short of what is needed, it is going to mean a cutback on fighting this epidemic in India.

Let me also address the cutbacks in the budget relative to TB and malaria, a cutback of some \$46 billion. I have been to India just a few weeks ago to see DOTS, the Direct Observed Therapy, and it is done on the cheap. I saw it in a shoe store in one of the poorest neighborhoods in New Delhi.

How can we, in light of the fact that TB is such a killer and linked so many times to HIV/AIDS, how can we rationalize or justify cutting back in our commitment to TB and malaria?

Ambassador TOBIAS. Well, TB and malaria are very important components of the program. Testing people who have HIV to determine whether or not they have TB and can be put into TB programs is a very important component of this. We do need to stay very focused on TB and malaria.

Senator DURBIN. We need more than focus; we need money. Focus is good; money is better. In this situation, a little bit of money goes a long, long way. Ten dollars for the therapy to deal with tuberculosis, and the observation of a shoe store owner of a person taking their medicine has created a health infrastructure

which nobody knew could exist in this country, this vast country of India.

I am just troubled by the fact that with such facility we talk about \$25 billion more here and \$50 billion more there, and when it comes to these issues of the war on AIDS and the war on tuberculosis, frankly, we are talking about a hollow army and a hollow commitment. I think we can do better. I think the President called on us to do better. But frankly, the President's rhetoric is not matched by his budget numbers, and people will die as a result of that.

Ambassador TOBIAS. Well, we are very much on a path to meet the President's commitment of \$15 billion over 5 years and we are implementing the needs in people and infrastructure in a very aggressive way. I think as we get more health care system improvement in place we are certainly going to be able to implement more quickly.

Senator DURBIN. My last point—thank you for your forbearance, Mr. Chairman—is that is an argument I categorically reject, and here is how it goes: We cannot give them the money; they do not have the health infrastructure. Well, how do you get the health infrastructure? You start training people to be doctors and nurses and medical professionals. You start setting up clinics.

How are they going to do that? Is this supposed to spring just automatically? I think we have to invest in the infrastructure to deliver the drugs, to bring the people in, to monitor their activity, for public education. To say we are going to wait on the infrastructure before we send the money means basically we may not ever send the money.

Ambassador TOBIAS. Well, we are not waiting on the infrastructure. That is exactly where the initial money is going, is to help build the health care systems and the infrastructure. The greater operating expense going forward is going to be the things that we put into that system.

But there is no question that the magnitude of this problem is well beyond what this program is focused on and we need to get more help from everybody that we can find that will provide help.

Senator DURBIN. Thank you.

Senator McCONNELL. Thank you, Mr. Tobias.

Thank you, Senator Durbin. We are going to complete your appearance right now, Mr. Tobias. Any Senators who wish to submit questions in writing, may do so. We have a vote at 11:30, so what I am going to do is to have a very short recess. We are going to catch the vote. We will come back and have the second panel as soon as I return, which will be shortly.

Senator LEAHY. Mr. Chairman.

Senator McCONNELL. Senator Leahy.

Senator LEAHY. If I might, there will be questions for the record. I would just let Ambassador Tobias know that one question I will ask, and I really want a straight answer on this, is that we have been told that even though the administration's own experts have rated some of the faith-based organizations very, very low as to their abilities, they are getting preference for funding.

I have some faith-based organizations I feel highly about. But what I feel most urgently is to do something to stop AIDS, and I

do not want to think, with all the money we are doing, that it is being passed out as a political goodie. So look at my question. It is a very, very serious one.

Senator McCONNELL. All right. We thank you, Mr. Tobias. We will take a brief recess and then resume the hearing shortly.

**STATEMENT OF BONO, FOUNDER OF DATA, DEBT AIDS TRADE AFRICA
ACCOMPANIED BY AGNES NYAMAYARWO, NURSE AND AIDS ACTIVIST,
UGANDA**

Senator McCONNELL. This hearing will resume.

Our second witness needs no introduction. In this town he is known as much for his music as he is for his work on behalf of HIV/AIDS and debt relief. He is an effective spokesman for these causes and his political skills are as good as any on this subcommittee, perhaps even better.

So welcome, Bono. I understand that with you is Ms. Agnes Nyamayarwo, a nurse and AIDS activist from Uganda. I will leave the formal introduction of her to you, but I would request Ms. Nyamayarwo take a seat next to Bono, if you will. We want to give our colleagues an opportunity to ask questions to someone whose personal insights will undoubtedly be very, very helpful.

Before you make a brief opening statement, let me take a moment to thank you for your eloquent description in Time magazine, Bono, of a woman we both admire and support, Burmese democracy leader Aung San Suu Kyi. Last week she, the National League for Democracy and ethnic nationalities made the courageous and correct decision to boycott the junta's sham constitutional convention in Rangoon.

I unabashedly use this opportunity, while the spotlight shines on a high-profile activist such as yourself, to highlight her plight. At this critical moment she and the people of Burma need the world's attention and support. I am pleased that the United Nations, the European Union, Japan, Malaysia, and Thailand have expressed concern with the regime's unwillingness to move forward in a meaningful reconciliation process with the NLD and the ethnic minorities.

The Burmese people should find encouragement from these remarks. As we approach the anniversary of Burma's 1990 elections and last year's massacre, which almost took Suu's life, I would urge my colleagues in both the Senate and House to quickly renew import sanctions against the junta. Bono, I know you agree that we cannot fail Suu Kyi or freedom in Burma.

Senator Leahy will be back shortly and I will allow him to make his comments then. I think what we will do is proceed, Bono, with your opening remarks.

BONO. Thank you very much. Thank you very much, Chairman McConnell. It is an honor to be asked to share my thoughts today. I would like to thank friends Leahy, DeWine, and Durbin. When they come back I will. They have shown great leadership on this subject and, I have to say, patience in dealing with a rock star, and a rock star who asks for a seat at your distinguished table, then refuses to leave. And frankly, there is a lot of people who wish I had stayed in the studio, including my band.

But you let me in the door. You let me in the door on debt relief. We have worked together on AIDS and the Millennium Challenge. And now I am going to abuse your hospitality by hanging around, talking loudly, when you really ought to be hearing from people who truly live the subject, like Jim Kim at the World Health Organization or a treatment advocate like Zackie Achmet in South Africa, or indeed a true heroine like Agnes here, whom many of you know.

But I promise to talk briefly and politely. I think it is really brilliant to be here, and my testimony will be suitable for family audiences. Your children, your country, are safe, safe from my exuberant language.

I have just come back from Philadelphia and it was an extraordinary day there yesterday with various religious groups and student activists. We are putting together a campaign to unite everybody all across the country, all across the United States, to unite the country under this issue of AIDS and extreme poverty.

I think we are going to succeed. You listen to these people talk about America taking the lead on this and you would be very proud. I think they know—their message to me was: This is a critical time. And I think we all agree with that.

We are making progress in the fight against AIDS. We are gaining speed, building momentum, but only as long as we keep our foot on the gas, because, Senator, as you know, we have a lot more road ahead. Our success so far should make us confident, but it cannot make us content. We are off to a great start. Only you here can make sure that it is not a false start. If we stop at AIDS, oddly enough, we will not beat AIDS, because we need to do more about the conditions, the extreme poverty in which AIDS thrives.

But lest this sound like a burden or “more money, more money,” can I just say this is actually the exciting bit, because we can use this disease to knock poverty out. This is an incredible opportunity for America. I am not a Pollyanna on this stuff. I have seen it work. I have seen it save and transform lives.

Just at this moment in the world, it just feels important, as a fan of America, to see America knocking poverty out and taking the lead on AIDS. I think it is a great, great message.

So let me talk a little bit about the results that we are seeing, because a few years back I was here to talk about debt cancellation and I think it is important that I give you a report back on what we did with that money. I remember sitting in your office, Senator McConnell, and going through this, and you were listening to this. It was my first sort of foray here and you were very patient with me as I had my hand in your wallet.

But I feel an obligation to explain to you all on this committee what we did with that money, because it is an astonishing thing, and I hope America is aware of what it did. There are 27 countries who had chronic debts owed to the United States from way back and they have been cancelled. With that money there has been astonishing results.

Three times the amount of children, where Agnes is from, three times the amount of children going to school. What an astonishing thing. I have even had Senator Frist witness some of this stuff. Together we saw water holes built by moneys freed up by debt can-

cellation. When others said the money was going down a rat hole, in fact it was going down a water hole. A very, very proud moment for me and I hope for America.

So more recently we have been working together on the Millennium Challenge, something we worked on with this administration and then across with support on both sides of the aisle. This is important stuff and I am not sure people have—it has really sank in what the Millennium Challenge was all about. It is important. It is a paradigm shift because it is rewarding countries that are fighting corruption and that are actually tackling poverty and the poverty of their people.

Because wherever we go in America, that is the only issue we hear about that makes people cautious about development assistance. They want to know that the money is going to the people it is promised to. So corruption is absolutely essential that we deal with.

The Millennium Challenge is this kind of new way of seeing aid as a reward for people who do the right thing. Where there is civil society, clear and transparent process, good governance, let us fast track those people. It is common sense and, by the way, it is going to be imitated around the world and it was invented here in this city. It is a new paradigm shift, deserves a lot of support.

The President asked you for \$2.5 billion for 2005 and I figure that is a little more persuasive than my asking you, but I will just urge you to support him on that. DATA, D-A-T-A, the organization I helped start, has found that the 16 well-governed poor countries selected for the Millennium Challenge, are ready to use all of that funding on sound poverty reduction plans. They need only what you can give them, which is really a chance. So it is a good start, but only that, a start.

We are not here today for a victory lap. We are here to pick up the pace, because AIDS, as Senator Durbin mentioned, is outrunning us. It is killing 6,500 Africans a day, 7,000 Africans a day. Whoever you are talking to, the number is hard to stomach. 9,000 more Africans a day infected.

The most incredible part about this is it is fully preventable and treatable, which is an incredible opportunity for America. As I say, at this moment of all moments, when people are not necessarily sure about us in the West that our intentions are benign even in Europe and America, there is a lot of suspicion about our intentions in the rest, in the wider world, this is an incredible opportunity because America has the power to make this stop. It is an achievable goal.

There will soon be a day when AIDS is gone. There will be a vaccine, it will be gone. I think when the history books are written, would it not be nice to see the United States right out in front. Like going to the Moon: We did it first, there it is.

The tough thing about this realization that we have the power to make it stop is that it means we have actually got to do something about it. For the first time in history, we have the know-how, we have the cash, we have the life-saving drugs. Do we have the political will?

Ambassador Tobias does. As we heard, he sees the fire raging and he has got a fire brigade. That is a great thing. He needs your

support, fully funding of around \$2.5 billion for the bilateral programs. Every dollar counts.

That is why the debate over generic medications is so frustrating, because when there is a fire raging you do not fight it with bottled spring water; you turn on the hose and put the fire out. There are safe generic drugs saving lives right now at a fraction of the price of their brand-named twins. Here is an advert for one sitting right beside me, someone who is a great advertisement for those generic drugs. And we have to ask the experts, like Medecin Sans Frontier, one of the first people to involve ARV's in the treatment of AIDS. They are doctors. They believe it is safe.

I think what we talk about—President Bush when he spoke about AIDS he was very inspiring because he spoke about bicycles: We will get them on bicycles and motorcycles. This is exactly the tone, this is what we need. But the bicycles right now are wrapped in red tape, is the truth, and we need to cut through the red tape. We need the spirit of that announcement of \$15 billion over 5 years in the actual follow-through.

So we have this news in the last couple of days that could be great news, that we are considering generics and fast-tracking a breakthrough on generics in 6 weeks. But this is, 6 weeks of red tape, is very costly. That is 250,000 lives. So I would just caution us, this 6 weeks.

So Americans want the biggest bang for their buck, that is true. They want to treat as many people as possible. Let us get together on that and make sure they get the biggest bang for their buck.

Every dollar counts, but some dollars count for triple. By this I am talking about the Global Health Fund, an essential part of the fight and a vital partner to what the United States is doing. Every contribution America makes gets other countries to kick in more. Tony Blair says so, so does President Chirac, so does Paul Martin. I know because I have spoken to all these people recently. I make their lives miserable, too, you will be relieved to hear.

But to date the United States has made one-third of the fund's contributions. I would urge you to maintain that commitment in the neighborhood of \$1.2 billion for next year. Yes, the fund has growing pains, but the fact that it is growing in scale and in impact, not only on AIDS but on other killer diseases that worsen it like malaria and TB, is encouraging.

Of course miracle drugs alone are no miracle cure. We cannot defeat AIDS unless we do more about the extreme poverty in which it spreads. Otherwise our efforts will come to naught. You cannot take a pill if you do not have water to swallow it, clean water that is. You cannot strengthen your immune system if there is no food in your belly. And you cannot teach kids to protect themselves if they do not go to school. That is why the Millennium Challenge and other key programs you fund through USAID are essential.

More investment is needed, a lot more investment is needed. President Bush has asked for a lot more, over \$21 billion in total for foreign ops in 2005. I think that is because he, like many of you, sees that a victory in this battle is vital to national security.

Our issues, people tend to think of them as fringe, not central to the action here in Washington, D.C. If I can convince you of one thing, it is that at this time in the world these issues that you have

gathered to talk about on this committee has a role to play in very central policymaking that will affect the way America is viewed everywhere in the world. It is where America meets the world, outside of commerce and the military.

The Senate, in passing a bipartisan budget resolution, has gone a step further on these issues, and I applaud that. I trust the Senate will hold on to increases in the appropriations process. I do want to say thank you personally to the Senate for their leadership here and all of you sitting here. It is very, very, very important.

Let me say this in closing. I know I spend a lot of time in this country and I am sure it is too much for your liking. But I also spend a lot of time in buses, truck stops, town halls, church halls, and I am not even running for office. But I have spent a lot of time in this country campaigning on these issues.

You know what is amazing? Everywhere I go, people feel more American when you talk about these issues that affect people whom they have never met and who live far away. They feel more American. It is kind of extraordinary to me as an Irishman to observe this.

I think that they are thinking big, as you always have. Sixty years ago there was another continent in trouble, my continent Europe in ruins after the Second World War. America liberated Europe, but not just liberated Europe; it rebuilt Europe. This was extraordinary. And it was not just out of the goodness of your heart, which it certainly was. It was very smart and strategic, because the money spent in the Marshall Plan was indeed wise money. It was a bulwark against Sovietism in the cold war.

It was 1 percent of GDP over 4 years, I believe. I would argue that this stuff we are discussing today is a bulwark against the extremism of our age in the hot war. I believe there is an analogy.

I believe brand USA, because all countries are brands in a certain sense, never shone brighter than after the Second World War, when a lot of people in my country and around the world just wanted to be American—wanted to wear your jeans, wanted to listen to your stereos, wanted to watch your movies. That was because this is an astonishing place, America.

It cost money, that place in the world, I know, and I know how expensive the Marshall Plan was—point one. We are looking for numbers that I think are about half that to completely turn the world around at a time—on a positive thing, like a health crisis, making that a positive thing. So please bear with us.

In turbulent times it is cheaper and smarter to make friends out of potential enemies than to defend yourself against them. A better world happens to be a safer one as well. I think it is a pretty good bargain.

PREPARED STATEMENT

The attention of the world might sometimes be somewhere else, but history is watching. It is taking notes and it is going to hold us to account, each of us. There is so much you can do with your power, with your leadership, to ensure that America here is on the right side of history. When the story of these times gets written, we want to say that we did all we could and it was more than anyone could have imagined.

Thank you.
[The statement follows:]

PREPARED STATEMENT OF BONO

Thank you, Chairman McConnell. It is an honour to be asked to share my thoughts today. Let me also thank some very good friends: Senators Leahy, DeWine, Durbin and so many others who have shown such leadership on these issues.

And such patience in dealing with a rock star who asks for a seat at your distinguished table, then refuses to leave or to turn down the music he's blasting. Frankly there are a lot of people who wish I'd stay in the studio—including my band.

You let me in the door on debt relief; we've worked together on AIDS and the Millennium Challenge; and now I'm going to abuse your hospitality by hanging round and talking loudly when you really ought to be hearing from someone who knows better—a medical doctor like Jim Kim at WHO, or a treatment advocate like Zackie Achmet of South Africa, or a true heroine like Agnes, here, whom many of you know.

That said, I promise to talk briefly—and politely. Though I think it's really brilliant to be here my testimony will be suitable for family audiences. Your children, your country, are safe from my exuberant language.

I've just returned from your nation's first capital—Philadelphia—where my organisation, DATA, and an array of other groups launched a new effort we're calling "The ONE Campaign." These organisations represent millions of Americans, from evangelicals to student activists. They came from all over the country. And they're speaking with one voice in the fight against AIDS and extreme poverty.

What are they saying?

They're saying—as I think we all agree—this is a critical moment.

We're making progress in the fight against AIDS. Gaining speed. Building momentum. But only as long as we keep our foot on the gas. Senators, as you know, we've got a lot more road ahead.

Our success so far should make us confident. But it can't make us content. We're off to a great start—but only you can make sure it's not a false start. If we stop at AIDS, we won't beat AIDS. We need to do more about the conditions—the extreme poverty—in which AIDS thrives.

Now, I'm not a Pollyanna on this stuff; I've seen it work. I've seen it save and transform lives. So let me talk briefly about the results we're seeing.

As I mentioned, I met many of you a few years back when we worked to cancel the debt that burdens the poorest countries. Today, 27 countries—almost all in Africa—are investing that money in schools, vaccinations, and roads instead of in debt payments. In Uganda, I've stood with Senator Frist at a clean water well built thanks to debt relief. Debt money didn't go down a rathole—it went down a waterhole.

More recently, we've all worked together on the Millennium Challenge. This is smart money, new aid in new ways, rewarding poor countries who are leading in the fight against corruption. Though it's only just up and running, it's already having an impact, encouraging countries to reform.

The President has asked you for another \$2.5 billion for 2005. I figure that's a little more persuasive than my asking you, so I'll just urge you to support him on that. DATA, the organization I helped start, has found that the 16 well-governed poor countries selected for MCA are ready to use all of that funding on sound poverty reduction plans. They need what only you can give them: a chance.

All in all, then, we've made a good start. But only that. A start.

We're not here today for a victory lap; we're here to pick up the pace. Because AIDS is outrunning us, Senators; it's killing 6,300 Africans a day, infecting 8,800 more Africans a day; and the most incredible part is it's fully preventable, it's fully treatable.

We actually have the power to make this stop. But the tough thing about that realization is that it means you've actually got to do something about it. For the first time in history, we have the brains, we have the cash, and we have the life-saving drugs. But do we have the political will?

Ambassador Tobias does. As we heard, he sees the fire raging and he is leading a fire brigade, and that's a great thing. He needs your support, full funding of around \$2.5 billion for bilateral programs.

Every dollar counts. That's why the whole debate over generic medications is frankly frustrating. When there's a fire raging, you don't fight it with the finest spring water. You turn on the hose and put the fire out. There are safe generic drugs saving lives right now at a fraction of the price of their brand-name twins.

I know that Americans want to get the biggest bang for their buck: to treat as many people as possible. That's the whole point, right? If that's your goal, isn't the administration's position on generics untenable? Hopefully this is starting to change, we still need to hear the details.

As I said, every dollar counts, and some dollars count for triple. I'm talking about your contributions to the Global Fund—an essential part of the fight and a vital partner to what the United States is doing. Every contribution America makes gets other countries to kick in more. Tony Blair says so. So does President Chirac. So does Paul Martin. I know because I've been making the rounds with the tin-cup in those countries too.

To date, the United States has made one-third of the Fund's contributions—I urge you to maintain that commitment, in the neighbourhood of \$1.2 billion for next year. Yes, the Fund has had growing pains, but the fact is it's growing—in scale and in impact: not only on AIDS but on the other killer diseases that worsen it, malaria and TB. Combined with bilateral, this is about \$3.6 billion which is allowed under last year's law.

Of course, miracle drugs alone are no miracle cure: we can't defeat AIDS unless we do more about the extreme poverty in which it spreads. Otherwise our efforts will come to naught. You can't take a pill if you don't have clean water to swallow it. You can't strengthen your immune system if there's no food in your belly. And you can't teach kids to protect themselves if they don't go to school.

That's why the Millennium Challenge and other key programs you fund through USAID are essential. More investment is needed a lot more. President Bush has asked for a lot more—over \$21 billion total—for Foreign Operations for 2005, because he, like many of you, I think, sees victory in this battle as vital to your national security. The Senate in passing a bipartisan budget resolution has gone a step further on these issues, and I applaud that. I trust the Senate will hold onto its minimum amounts and keep up the pressure for more.

Let me say this in closing.

Senators, I spend a lot of time in this country. Maybe too much for your liking. I spend a lot of time in buses. At truck stops. In town halls. In church halls. I do all this, and I'm not even running for office.

But you know what's amazing? Everywhere I go, I see very much the same thing. I see the same compassion for people who live half a world away. I see the same concern about events beyond these borders. And, increasingly, I see the same conviction that we can and we must join together to stop the scourge of AIDS and poverty.

Americans are thinking big. As you always have. You know, almost 60 years ago, another continent was in danger of terminal decline—not Africa, but Europe. And Europe is strong today thanks in part to the Marshall Plan. It was great for Europe, but it was also great for America. Brand USA never shined brighter.

Today we need the same audacity, imagination, and all-out commitment of a modern Marshall Plan. The Marshall Plan built a bulwark against Communism; today, for half the cost, we can build a bulwark against the extremism of our age.

In turbulent times it's cheaper, and smarter, to make friends out of potential enemies than to defend yourself against them. A better world happens to be a safer one as well. That's a pretty good bargain.

The attention of the world might sometimes be elsewhere, but history is watching. It's taking notes. And it's going to hold us to account, each of us. There is so much you can do, with your power, with your leadership, to ensure that America is on the right side of history. When the story of these times gets written, we want it to say that we did all we could, and it was more than anyone could have imagined.

Thank you.

Senator McCONNELL. Thank you very much, Bono.

Ms. Nyamayaro, I see that you have a piece of paper in front of you. Do you want to make a brief statement as well?

SUMMARY STATEMENT OF AGNES NYAMAYARWO

Ms. NYAMAYARWO. Thank you so much. I am happy to be in this house today. I want first of all to introduce myself. I am Agnes Nyamayaro. I come from Uganda from an AIDS organization called TASO, the AIDS Support Organization in Uganda. I am a nurse and working as a volunteer with this organization.

I have lived with HIV for 15 years. I want to share with you briefly what happened to my family with the AIDS epidemic. My

husband died of AIDS in 1992. My youngest son died of AIDS at the age of 6½ because I passed the virus to him unknowingly. You can imagine as a parent giving a death sentence to a child. It is very painful.

My other son, who was age 17, got overwhelmed by the problem of AIDS in the family and suffered depression and he disappeared from my family and up to today I have never seen him again, still searching for him.

I have been very lucky. I have been on treatment, antiretroviral treatment. I started by taking generic drugs and now I am on the branded drugs from TASO, which is supported by the U.S. Government, and I am very grateful for that. Actually, I see that they work the same, because I was down and I started with generic drugs and they improved my life, and now that there are branded drugs I started taking branded drugs and they work exactly the same.

Last year in July I met with President Bush and I told him I was in treatment and my life had improved, but my concern is the other people living with HIV in Uganda and in Africa who die every day. And every time I go back to the community, where we move around creating awareness about HIV/AIDS, I find so many people have died, so many people dying. That is very painful indeed.

The President promised that he was going to give treatment to all people living with AIDS in Africa quickly and immediately. It is almost a year now. We have just got money to start on treatment on not even a quarter of the people in my organization. So it has given me hope, it has given us hope, all of us. But we are still asking for more.

In my work with DATA I have been in about 10 States in America. It exposed me to many Americans and their response was excellent and they were willing to help. This has always given me a lot of hope, although every time I go back my people think I have carried medicines for them. But I tell them: I have hope; Americans are ready to help.

Today I am here to request this house as you are going to make decisions on the programs to fund just to remember me, my family, and all the people living with HIV in Uganda and Africa, and the many orphans in Africa, and the young people who need the education, because the more they keep in school the more they delay to get infection, and the more they are educated the more they know about how they can avoid catching HIV. So good education is very, very important.

Then we also have that problem of poverty. Even with the mother-to-child transmission, mothers are given the medicine to reduce the infection, but these mothers have to give the formula and they do not have the formula. They do not even have the money to buy it. Or if they have it, they may mix it with dirty water and these children end up dying of diarrhea. So clean water is also very, very important.

I am still also asking you to really look at the trade with Africa. It is very important because one day maybe we shall be able to stand on our own. So please, help us fight AIDS and poverty in Africa.

Thank you so much.

Senator MCCONNELL. Thank you very much.

Even though this hearing is about HIV/AIDS, I do want to address once again, Bono, an issue that you and I are extremely interested in. For the record, do you support renewal of import sanctions against the Burmese junta, as Senator Leahy and I have proposed?

BONO. I do not just support it; I applaud it as loudly as I can. Let me say, your leadership on this—there is no one leading support for Aung San Suu Kyi like you, and to have Senator Leahy by your side, and make sure that this is the support of all Americans is amazing.

These toenail-pullers, these thugs, are also running this country like a business, so the place they will feel the pain is in business. Sanctions are crucial.

Senator MCCONNELL. One of my big frustrations, which I know you share, is that the only way sanctions are going to really have an impact is if they are multilateral. Is there anything we could do that we are not currently doing to convince the European Union that a tougher approach ought to be in place toward the generals in Rangoon?

I had hoped that the attempted assassination of Suu Kyi last year might have gotten their attention, but apparently not. What thoughts do you have about how we get the Europeans fully engaged in the sanctions regime?

BONO. I am deeply ashamed as a European of the pitiful lack of volume in support for her. I think Prime Minister Blair has been doing some good work, but we need more and we need the rest of Europe to pay attention. I will personally speak to Roman Prodi, who is the President of the European Union, about this and see at their next meeting if we can get a resolution.

Senator MCCONNELL. In your statement you indicated that America must have the political will to combat HIV/AIDS. How do you cultivate political will in countries that do not respect the basic rights of their citizens? In Burma, for example, where, instead of stopping HIV/AIDS and poverty, the junta may actually be spreading the disease and misery through rape, forced labor, and illicit narcotics?

BONO. I think what is extraordinary about the Millennium Challenge Account, which I was talking about earlier, is that it provides assistance for countries who are doing the right thing by their people and tackling corruption, etcetera. I think with Burma we have a particular evil to deal with that needs a different and stronger response.

So I would suggest sanctions. I think they should be punitive and I think those people should feel our mettle. They cannot walk over this woman, who is a true hero. In a way, with the Millennium Challenge we are trying to encourage the kind of leadership she represents. This is the future in the end for all of the issues that we are talking about today, is leadership. Leadership is everything.

Even with AIDS, we talk about A, B, C. What is important is a balanced approach. But you know, the reason why abstinence and these kinds of programs, preventive programs, worked in Uganda was because of another letter "L", "L" for leadership and "L" for

local, understanding the local. To me, Aung San Suu Kyi is great leadership.

Senator MCCONNELL. Ms. Nyamayawo, in Cambodia sex workers refused to participate in a Gates Foundation-funded anti-HIV drug test because of concerns with potential long-term health impacts. How do we ensure that impacted groups, such as Cambodian sex workers, have the will themselves to participate in education and treatment programs?

Ms. NYAMAYARWO. Back in the country where I come from, they have been asking us about the sustainability of this treatment and that was—maybe that may have been the same reason why in Cambodia these people are not going in for this treatment. But as a person living with HIV I told them that for me if I live another 5 years for my children that is very important indeed, because they will have the guidance from me and the parental care.

So I think maybe we need to, Uganda needs to go and share with those people what is happening in Uganda and what we people living with HIV in Uganda feel about this treatment.

Senator MCCONNELL. Thank you.

Senator Leahy.

Senator LEAHY. Thank you, Mr. Chairman.

Bono, you and I have been friends for many years. I think we also, on this Appropriations Committee, we also sit on the question of money for terrorism, and of course if somebody comes up and says this is for terrorism we can find enormous amounts of money.

But I was struck by something you said in your statement, and I wrote it down: A better world is also a safer world. That really goes to the bottom line on everything you are trying to do. You have seen probably more than anybody this effect of AIDS and what is being done to combat it. You have traveled everywhere.

You heard me ask Mr. Tobias about the potential of these countries to absorb more funds. Can they absorb more funds? And if they can, what would they spend it on? What should they spend it on?

BONO. You know, we use this word “absorptive capacity” a lot, but the truth is there is a distributive capacity problem. I think what I object to sometimes was when it is characterized as, oh, Africa or whatever country in Africa or elsewhere, they just could not take the money, so it is kind of their fault. I object to that.

I think what we should say is: Yes, there are difficulties spending the money effectively and efficiently, but we have to spend on building the capacity. That is what you do in an emergency, in a war. You have to build the infrastructure. And this is a war against AIDS.

What is great about this war is we really are going to win. The only opposition is our own indifference.

Senator LEAHY. But you also have a chicken-egg sort of thing.

BONO. Yes.

Senator LEAHY. You say building the capacity, but that can be done. There are models for doing that in parts of the world, bringing in everything from the roads to the training. We are not talking about building Johns Hopkins in every village that we see.

BONO. No.

Senator LEAHY. But the basics are so absent. And I agree with you, we could be doing more.

We are somewhat limited in time and I know you have to leave. An area that we are aware of, we do not talk enough about: What about AIDS orphans? What do we do to help the AIDS orphans?

BONO. There is your chaos right there. Again, maybe sometimes it is obvious. It sounds grating to always describe, to describe the war against poverty as being connected to the war against terror, but I did not say that; Secretary of State Colin Powell said that. And it is very wise when a military man starts talking like that.

There is a connection. We have a situation now—and I have seen it first-hand myself—where you have children bringing up children. And we should see Africa as not the front line in the war against terror, but it might be one day. You take a country like Nigeria, Nigeria is an oil-wealthy nation. It has 120 million people. It is the whole of west Africa, essentially. In northern Nigeria every week a new village falls under sharia law and they are then—we have the madrassas, we have the schools that teach them to hate us.

So these groups, they take advantage of the chaos, though in northern Nigeria the chaos is not as great as it is in southern, in some of the southern African countries. It is an example, the AIDS orphans is an example of the chaos waiting for order to be brought to it, either by them or by us. I am arguing that it is cheaper to prevent the fires than to put them out later.

Senator LEAHY. Oh, I agree with you.

Mrs. Nyamayaro, like you my wife was trained as a nurse, and I appreciate our conversations we had before this hearing. I do not know if I mentioned to you, we traveled to Uganda back in 1990. We visited a TASO center. We met HIV-positive volunteers there. In fact, most of the volunteers were HIV-positive. We were so impressed by their courage, their selflessness, and the fact they were helping others even though they were living under a death sentence.

In Uganda, if you could just take that one country, what has worked best in combatting AIDS? What could you use the most?

Ms. NYAMAYARWO. In Uganda it is not one thing, but first we have the good leadership of our president who has been open about HIV and AIDS and accepted to support us. The government has involved people living with HIV, and people living with HIV have got the heart to save other people's lives, like the volunteers in TASO. Myself, after losing my child to AIDS, I felt I should go out with those volunteers and talk to people, talk to parents, so that they do not go through what I went through, because it was very difficult for me, to try to save lives, go to schools and try to save the youth, to know more about HIV/AIDS.

I think the education has been very, very important on this issue. That is why I feel that education is real great. Then there is one problem which still stands, is the poverty. The orphans remain vulnerable. It is going to be like a circle, re-infection, because they do not have the support. Debt cancellation helps children to go to school just through primary. They cannot go to secondary schools, they cannot go to technical institutions. If all that is in place, I think we shall be able to really fight AIDS in Uganda.

Senator McCONNELL. Thanks.

Senator LEAHY. Thank you very much.

Senator MCCONNELL. Because of the lateness of the hour, we are going to do one round of questioning and we will have to submit the others.

Senator DeWine.

Senator DEWINE. Mr. Chairman, thank you very much.

Mrs. Nyamayaro, thank you very much for your very compelling testimony. We just very, very much appreciate it.

Bono, thank you very much for being with us again. Again, very compelling testimony as well. You have really been at the forefront. If you look at the issues that matter, the Millennium Challenge, you have advocated for that. Debt relief, that matters so very much. AIDS. All three of those issues, you have been there. You have been a leader.

Your testimony today I think has been so compelling because you have talked about AIDS from really a holistic point of view, that we cannot just look at AIDS separately; we have to look at it from the point of poverty, we have to look at it from the point of view of the whole medical system when we go into these countries that is connected to everything else.

You truly understand this issue. You have done such a good job, I think, of focusing the public's attention on AIDS. I would just ask you, as you have gone around, not just in the United States, but in other countries, what works and what does not work when you are either addressing people in towns in the United States or when you are dealing with leaders in other countries? What is compelling and what is not compelling when you talk about this issue? What works and what does not work? And how are we doing with other countries, too?

BONO. I think we need both bilateral and multilateral, is the truth. But we need them, we need everyone talking together. What does not work is when we play politics with people's lives. When everyone can get—when there is a parity of pain and sort of parity of applause—I think it is important there are people in other countries who are doing a lot more as a percentage of their GDP than the United States, and they get very upset when, just because the United States is giving more money—they say, well, hold on a second; we are spending a lot more as a percentage. So that does not work.

I think some humility in saying we have different ways of doing things, but we want to work together and we are not trying to score points, that works. I think this is an opportunity to unite people in a way that there is very little else out there to. I think you have—what else are President Chirac, President Bush, and President Blair going to agree on?

This is the one thing they can all hold hands on, and I think that might be a good symbol right now in the world. Maybe not holding hands, but—and I think seeing the historic side of things works. To tell—I know it is an absurd, an Irish rock star to do this, but to explain that when the dust settles and when the history books have been written, this entire era will be remembered for probably three things: the Internet, the war against terror, and what we did or did not do about this AIDS virus and what it did, what it did.

It will be astonishing, like your children, like me, reading about the bubonic plague in the Middle Ages, which took a third of Europe. A third of Europe died from the bubonic plague, the Black Death. Now, imagine if China, say, had treatment at that time that could have saved those lives, but did not get it out there because, ah, it was a little difficult and it was expensive. How would we be reading about China now? That is the position we are in. That is where Europe and America is right now, and I think it is a great opportunity.

Senator DEWINE. Thank you very much.

Thank you, Mr. Chairman.

Senator MCCONNELL. Thank you, Senator DeWine.

Senator Durbin, you are it. After you finish the hearing is completed except for whatever questions that we may want to submit. So if you would proceed.

Senator DURBIN. That is a lot of pressure, Mr. Chairman.

Senator MCCONNELL. See how short you can be.

Senator DURBIN. Well, I thank you very much.

I want to thank our witnesses for your patience in waiting for us to vote and come back and do other things in an extremely important session.

Thank you for your leadership. I have told you, Bono, that you are a consummate pest on Capitol Hill and please keep up your good work, pestering us to be mindful of the rest of the world and what we are facing.

It is no, I think, revelation that over the past several weeks we in America have been embarrassed and ashamed by some of the disclosures in the world press. The President has said and we have repeated that what happened in that prison is not indicative of American values. What I have found interesting in your tour of Wheaton College and other places in my State was that time and again you have said that you find us to be a good and caring people, and as a good and caring people there are things that we can do to prove that premise.

I find the same thing when it comes to this commitment, when it comes to global AIDS. You really call on us to do our best and I think we should and we must.

I would like to ask you specifically on this Global Fund issue. I am very concerned. If we do not increase the \$200 million commitment in this budget to a much higher level, I am fearful that ongoing projects may be cut back and new ones will not even be considered. What has been your impression of the work of Global Fund and if they had to retrench and fall back the impact it would have on this battle?

BONO. There are some difficulties with the Global Fund right now, growing pains. I might suggest that some of those difficulties come out of an environment and a mood where they just do not want to make a mistake, because they know if they do make a mistake there is a lot at stake. I actually, I can understand their caution. They just do not want to screw up, and I think as a result things have moved a little slowly there.

However, they have in Richard Feachem a really great leader. They have in their structure of the organization a really great design. And I think in a funny way it is a very American design. It

is McKinsey Management. They have a 4 percent overhead. They have auditors in place, PriceWaterhouse, Stokes Kennedy Crowell, all these people. Where the money is being spent on the ground, they have cut deals with them to make sure that these things are being effectively operated.

Is there enough money out the door at the moment? No. But remember, they cannot—without having the cash in their bank, they cannot even have the discussion with the groups on the ground.

The most important message to get out to Americans about the Global Health Fund is it is not a new bureaucracy. They are just supplying people in the regions who have effective programs with more money. They are scaling them up. It is really important. Some people do not understand that.

So I think they are critical, they are extremely critical, because President Bush's brilliant AIDS initiative only applies to 16 countries. So this is the other side. This is the rest of the world. It has to work. It will work.

I tried to say to them, you know, you are going to make mistakes; it is wonderful that you are so careful, but actually you are going to make mistakes; relax just a little bit about that.

Senator DURBIN. If I might ask you one last question. I do thank the committee for their patience here. People here in the audience earlier were removed with signs relative to drug companies and pharmaceutical companies and how much they are doing. I have heard you say something which is kind of self-confessional about your own attitude in dealing and working with pharmaceutical companies and drug companies. Tell us now what you think is the appropriate approach to make certain that as quickly as possible affordable medications are in the hands of the poorest people in the world?

BONO. Okay. Well, let me just say I fully, fully understand the frustration of my friends behind me who have their hopes raised when they hear of a \$15 billion AIDS initiative and then have them dashed when they hear that none of the money is going to go to the cheapest drugs.

What I would say to this issue is we need the pharmaceutical companies, is the truth. We need their brains, we need their know-how, we need their scientists. But there is an opportunity for them here to compete that they have not as yet made. They could really be heroes of the hour here. We need them.

I want them involved, and I am not going to ask a business to behave like a philanthropy. I do not think we should do that. But make their profits. Sure, make their profits—just not on the greatest health crisis in 600 years, on the backs of poor people. I think they do a great business. I am happy for them to make profit on me, make profit on my friends, make profit on everyone in this room, in this country, but not on what is going on in the everyday lives of people like Agnes here.

So I would say these drugs are a great advertisement for America. I told President Bush: Paint them red, white, and blue, you know, whatever. Get them out there. They are the best of the West.

So that is my own position and I hope that is clear.

Senator DURBIN. Thank you, Agnes. Thank you, Bono.

Thank you, Mr. Chairman.

Senator McCONNELL. Thank you, Senator Durbin.
Thank you, Bono. Thank you, Ms. Nyamayaro. It is nice of you to be here and to tell your story. It was very helpful.

ADDITIONAL COMMITTEE QUESTIONS

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR MITCH McCONNELL

Question. Voices for Humanity (VFH), a Kentucky-based non-profit, is slated to receive funding from USAID for a pilot project on HIV/AIDS education in Nigeria using cutting edge information technology. I strongly encourage you to follow VFH's efforts in Nigeria.

What importance do you place in using cutting edge information technology to educate and inform illiterate or semi-literate populations?

Answer. The unprecedented goals set by the President's Emergency Plan for AIDS Relief—to provide treatment to 2 million persons living with HIV, to prevent 7 million new HIV infections, and to provide care to 10 million people infected and affected by HIV/AIDS, including orphans and vulnerable children, will require that we actively seek new approaches to addressing HIV/AIDS, including through the use of cutting edge information technologies to reach as many people as possible.

The Emergency Plan not only brings hope through the commitment of extraordinary resources, but, as important, the opportunity to find new and more effective ways to fight the HIV/AIDS pandemic—our approach will not be “business as usual.” We are committed to implementing programs that are responsive to local needs—countries and communities are at different stages of HIV/AIDS response and have unique drivers of HIV, distinctive social and cultural patterns, and different political and economic conditions. Effective interventions must be informed by local circumstances and coordinated with local efforts.

The Office of the U.S. Global AIDS Coordinator has met with representatives of Voices for Humanity to be briefed on their project in Nigeria and will be meeting with them again as the project is implemented.

Question. Faith-based organizations, such as Lott Carey International (LCI), have decades of experience working overseas and have cultivated broad contacts among indigenous organizations and groups.

A. What are your goals and objective for utilizing faith-based organizations in combating HIV/AIDS?

B. Do you have a recruitment plan or strategy to increase participation of these groups?

C. How many faith-based organizations currently receive funding for HIV/AIDS activities—from USAID and your office?

Faith-based and other organizations interested in combating HIV/AIDS have contacted the Subcommittee to complain that the process for securing funding under this initiative is NOT user friendly.

D. Are you aware of these difficulties, and what steps can you take to ensure that the funding process is less bureaucratically cumbersome?

Answer. In implementing the President's Emergency Plan for AIDS Relief, we have sought to fund a broad range of innovative new partners, including faith-based and community-based organizations, to bring not only expanded capacity but also innovative new thinking to our efforts. Faith-based organizations not only bring expanded capacity and innovative new thinking to our efforts, but they are also among the first responders to the international HIV/AIDS pandemic, delivering much needed care and support for fellow human beings in need. Their reach, authority, and legitimacy—like other organizations—identifies them as crucial partners in the fight against HIV/AIDS, and we are committed to encouraging and strengthening such partners.

Our intent in the initial, first round of grants under the Emergency Plan has been to move as quickly as possible to bring immediate relief to those who are suffering the devastation of HIV/AIDS. The Office of the Global AIDS Coordinator chose programs in the first round because they have existing operations among the focus

countries of the Emergency Plan, have a proven track record, and have the capacity to rapidly scale up their operations and begin having an immediate impact.

By initially concentrating on scaling up existing programs that have proven experience and measurable track records, an additional 175,000 people living with HIV/AIDS in the 14 initial focus countries will begin to receive anti-retroviral treatment. Prevention through abstinence messages will reach about 500,000 additional young people, and assistance in the care of about 60,000 additional orphans will soon commence in those same countries.

As of March 30, 2004, we have partnered or sub-partnered with some 45 faith-based organizations. Grants to these organizations total \$57,528,298 thus far, and we are committed to expanding our work with both new and current faith-based organizations as Emergency Plan implementation progresses.

We recognize that the windows for applications in our initial rounds of funding have been relatively quick, and anticipate that future rounds will allow more time for applicants to prepare and submit funding proposals.

Question. Repressive regimes that commit widespread human rights—such as the Burmese junta’s policies of rape, forced labor, and use of child soldiers—have a direct and substantial impact on the general health of the population.

A. What programs or projects can the Coordinator’s office support to better understand—and mitigate—the impact widespread human rights violations have on populations, including the failure to prioritize HIV/AIDS prevention and treatment in places such as Burma, China and Russia?

B. How can “political will” be cultivated in repressive countries to address the HIV/AIDS pandemic, or to ensure the treatment is provided on an equitable basis and not only to supporters of a regime, for example?

Answer. The Emergency Plan for AIDS Relief Emergency Plan is the largest commitment ever by a single nation toward an international health care initiative. The vision of the President’s Plan embraces a multifaceted global approach to combating the HIV/AIDS pandemic. Within this global framework, leadership is a fundamental lever to ensure that governments respect human rights and appropriately prioritize HIV/AIDS prevention, treatment, and care.

The mission of the U.S. Office of the Global AIDS Coordinator is to work with leaders throughout the world to combat HIV/AIDS, promoting integrated prevention, treatment, and care interventions. While we are proceeding with an urgent focus on 15 countries that are among the most afflicted nations of the world, we continue to pursue on going bilateral programs in more than 100 countries, including Burma, China, and Russia. Our Five-Year Strategy for the Emergency Plan, released in February, articulates our goals, including a commitment to encourage bold leadership nationally at every level to fight HIV/AIDS.

Under the Emergency Plan, USAID’s fiscal year 2004 budget for its South East Asia Regional HIV/AIDS programs includes an additional \$1 million for programs in Burma, primarily in Shan and Karen States, which border China and Thailand. We are committed to ensuring that our assistance is consistent with our primary objectives of supporting democracy and improved human rights in Burma. No assistance is being provided directly to the regime. Our support is channeled through established international non-governmental organizations, such as Medecins Sans Frontiers, renowned for their resistance to government interference. In conjunction with the President’s Plan, HHS recently launched its Global AIDS Program (GAP) in China, the offices of which HHS Secretary Tommy G. Thompson helped inaugurate in October 2003. In an unmistakable demonstration of leadership, U.S. Ambassador to China Clark Randt led the Embassy delegation and attended a ceremony at the rural village with the first recorded case of AIDS in China. In March 1998, the United States and Russia began collaborating to control the spread of HIV and other sexually transmitted diseases. Since then, the United States and Russia have steadily advanced joint programs for HIV/AIDS prevention and capacity building. At their bilateral summit meeting in September 2003, Presidents Bush and Putin committed to reinforce this joint cooperation and coordination. At the just held G-8 Summit in Sea Island, they reaffirmed the U.S.-Russian HIV/AIDS Cooperation initiative with focus on: prevention, treatment, and care; surveillance and epidemiology; basic and applied research, including vaccine development; bilateral policy coordination in Eurasia and with the Global Fund for AIDS, Tuberculosis, and Malaria; and involving senior officials in support of public-private partnerships to combat AIDS. Such leadership at the highest levels underscores the President’s commitment to ensure that all governments pursue appropriate national strategies to confront the HIV/AIDS pandemic as the global health emergency it is.

Regarding political will, as noted above, the Emergency Plan places a high value on leadership to persuade all governments to address the HIV/AIDS pandemic and to ensure that HIV/AIDS services are provided on an equitable basis to all comers

based on clinical eligibility, particularly with repressive government. We are committed to encourage our partners, including multilateral organizations and other host governments, to coordinate at all levels to strengthen response efforts, to embrace best practices, to adhere to principles of sound management, and to harmonize monitoring and evaluation efforts to ensure the most effective and efficient use of resources.

In the global battle against HIV/AIDS, it is imperative that the many actors coordinate their efforts and make maximum use of increasing but still limited resources. To this end, in April, the United States, through the Office of the Global AIDS Coordinator, was instrumental in achieving donor government approval for a set of principles dubbed the "Three Ones" by UNAIDS. These basic principles, aimed at coordinating national responses to HIV/AIDS and applicable to all stakeholders involved in country-level HIV/AIDS, are: one agreed HIV/AIDS Action Framework that provides the basis for coordinating the work of all partners; one National AIDS Coordinating Authority, with a broad based multi-sector mandate; and one agreed country level monitoring and evaluation system.

The "Three Ones" Principles provide a constructive framework for coordination while permitting individual donors to fulfill their own program goals and mandates and disburse money to partners in their own ways, without having any one government or organization claim exclusive ownership of the coordinating authority. For the Emergency Plan, our focus worldwide is anchored in care, treatment, and prevention available to all comers based on clinical eligibility.

Question. On March 9, 2004, Director of Central Intelligence George Tenet testified that HIV/AIDS continues to endanger social and political stability, and warned that the virus is gaining a foothold in the Middle East and North Africa, "where governments may be lulled into overconfidence by the protective effects of social and cultural conservatism".

Do you agree with the Tenet's assessment that HIV/AIDS is gaining a foothold in the Middle East and North Africa?

Answer. As it has around the globe, AIDS is certainly gaining a foothold in the region. Although the Middle East as a region has one of the lowest rates of HIV/AIDS infection (an estimated 0.3 percent) of its adult population, even this rate is higher than East Asia and the Pacific region, and by UNAIDS' estimates the Middle East and Near Asia has the second-highest rate of increase of HIV after the former Soviet Union and Eastern Europe. While not a health and social crisis presently, HIV/AIDS is a growing and potentially serious problem in the region.

Drug use is on the rise in the Middle East, and in some countries such as Bahrain and Iran, injecting drug use is the primary cause of HIV infection. Prevailing social attitudes, cultural norms and religious tradition limit discussion of premarital sex, homosexuality, and adultery, all sexual behaviors that contribute to the spread of HIV/AIDS. Civil society, which in many other regions actively combats the disease, has not yet taken up the HIV/AIDS problem in the region. Unsafe medical practices are also a mode of HIV/AIDS transmission in countries such as Algeria and Iraq.

The underlying vulnerability of the region, therefore, is significant, especially given rapidly changing social norms in many countries and exposure to high-risk behaviors for HIV/AIDS transmission. Poverty and pronounced gender inequality in the region are also drivers of the epidemic.

While not calling for large-scale interventions or program investments, the HIV/AIDS situation in the region needs to be closely monitored. Middle Eastern and North African governments need to be urged to assess the vulnerability of their own countries and respond appropriately. Leadership by religious and political leaders at all levels at this early stage of the epidemic is the most effective means to ensure that its potential destructiveness is not realized.

Question. AIDS orphans generally do not have access to education in Africa, which often requires the payment of a school fee.

Do school fees create obstacles to stemming the spread of the disease by excluding vulnerable segments of the population to both the traditional ABC's and "Abstain, Be Faithful, use Condoms"?

Answer. Many children in Africa, particularly those impacted by HIV/AIDS, are unable to attend school because their families do not have the resources to pay school fees. This is particularly an issue for children orphaned due to HIV/AIDS. As part of a comprehensive assistance package for children affected by AIDS, school fees are sometimes included. However, it is important to note that school fees are often only one of several barriers to accessing education, and the right intervention can only be determined at the local level.

Basic education is the linchpin for success in many of the U.S. Government's development activities, including family planning, child health and HIV/AIDS. In order to be successful in the fight against HIV/AIDS, it is essential that we wrap

all of our development programs around HIV/AIDS programs. We have been working around the world to integrate AIDS prevention messages into all of the other sectors, including education.

Question. Given Rotary International's superb work in combating polio internationally, do you have any plans to use Rotary—and its networks—to tackle HIV/AIDS, malaria or TB issues?

Answer. In implementing the President's Emergency Plan for AIDS Relief, we have sought to fund a broad range of innovative new partners to bring not only expanded capacity but also innovative new thinking to our efforts. We would welcome the opportunity to consider partnering with Rotary International in our efforts, especially in countries such as Kenya with strong local clubs. Health and Human Services Secretary Tommy G. Thompson traveled with the Chairman of the Rotary International Foundation, Jim Lacy, to India, Pakistan and Afghanistan in April 2004, and encouraged him to fund ways for the Foundation and individual Rotary chapters to engage with the President's Emergency Plan.

Question. The 2002–2003 outbreak of SARS in Asia highlighted deficiencies in mounting a concerted international response to a rapidly spreading disease. In a recent GAO report, delays in the initial response were attributed to China's reluctance to share information on SARS or to invite specialists to investigate the outbreak in a timely manner.

A. With respect to HIV/AIDS, are there particular countries that are less than willing to provide information or access to international medical specialists to help stem the spread of the disease?

B. Given that SARS underscored weaknesses in many Asian governments' disease surveillance systems and public health capacities—to say nothing of communications systems and effective leadership—how confident should we be that these same governments are capable of monitoring HIV/AIDS?

Answer. In Asia, as with other regions of the developing world, there has been a perceived reluctance on the part of some countries to share specific information, including numbers of HIV/AIDS cases, issues relating to safe blood supplies, and other information relating to the treatment and care of HIV/AIDS patients. There are a number of political, cultural, economic, and security reasons that influence some East and Southeast Asian countries to withhold valuable information during health and environmental crises and fail to seek appropriate outside assistance. In recent years, the world has increasingly acknowledged the dire threat that HIV/AIDS poses, not only as a health crisis, but also as a threat to economic growth, an overwhelming burden on health care infrastructure, and the potential for undermining national stability. Recently, there have been positive developments in Asia demonstrating a new level of political will to meet the challenges imposed by the pandemic. In addition, the inadequate response to the SARS epidemic served as an important lesson, particularly for China, on the consequences of inaction during a health crisis. Since the Severe Acute Respiratory Syndrome (SARS) emergency, China has significantly strengthened its political will to openly address the HIV/AIDS pandemic. China has formed the State Council Working Group on HIV/AIDS, which includes 21 ministries and has increasingly sought information on the most effective way to respond to HIV/AIDS, including dialogue on technical assistance to support the health care sector and health infrastructure.

With regard to monitoring for HIV/AIDS, along with an increased level of political will to effectively address HIV/AIDS, many Asian countries now recognize the importance of significantly improving data quality. For example, in China, the Global AIDS Program of the U.S. Department of Health and Human Services has a surveillance component as part of its technical assistance project in China. This will help the country develop systems to monitor rates of infection and the impact of prevention programs. The Chinese government is supportive of this type of technical assistance, and continues to work with donor countries and nongovernmental organizations to develop more effective strategies in the fight against HIV/AIDS.

Question. What weight do you put on efforts to combat malaria—which kills over 1 million people a year—and what is the role of your office in anti-malarial efforts of the U.S. Government?

Answer. As you suggest, opportunistic infections, such as tuberculosis (TB) and malaria, play a fundamental role in the overall health of HIV infected individuals. Malaria is the most common life-threatening infection in the world. It is endemic in more than 90 countries, and a child dies every 30 seconds from it, mostly in Africa. Causing more than one million deaths and 500 million infections annually, malaria impedes economic development in Africa, Asia, and the Americas. Because of the annual loss of economic growth caused by malaria, gross domestic product in endemic African countries is up to 20 percent lower than it would have been if there were no malaria in the last 15 years.

The Emergency Plan for AIDS Relief, will coordinate and integrate anti-malarial efforts into HIV/AIDS prevention, care and treatment. This is especially critical in the context of providing HIV care to pregnant women. Moreover, the Office of the U.S. Global AIDS Coordinator is committed to coordinating with the global anti-malarial activities of both the U.S. Agency for International Development and the U.S. Department of Health and Human Services.

QUESTIONS SUBMITTED BY SENATOR PATRICK J. LEAHY

Question. Do you agree that any faith-based organization that receives U.S. funds, if it provides information about condoms the information must be “medically accurate and include the public health benefits and failure rates of such use?” Do grant agreements with faith-based groups require them to adhere to this requirement, as Senator Frist and I recommended in a colloquy on the Senate floor? How do you plan to monitor adherence to the law?

I am told that funding for USAID’s commodity fund to purchase condoms has remained stagnant for several years, despite the steady increase in HIV infections. Do you plan to spend more on condoms in fiscal year 2005 than last year, or less?

Answer. In the Acquisition and Assistance Policy Directive dated February 26, 2004, the U.S. Agency for International Development mandates that information provided by any organization receiving funding—including faith-based groups—must be medically accurate. Specifically, the following wording is now included as a standard provision of all new agreements, as well as older agreements that add new funding:

“Information provided about the use of condoms as part of projects or activities that are funded under this agreement shall be medically accurate and shall include the public health benefits and failure rates of such use.”

Organizations not in compliance could be considered in violation of the terms of their agreement.

The Commodity Fund was established in fiscal year 2002 to remove financial constraints to the availability of condoms for missions who wish to make them available as part of their AIDS prevention programs. The amount allocated for this purpose increased in 2003, and then remained constant in 2004. Funding decisions have not yet been made for fiscal year 2005, but the importance of this resource is acknowledged. Total condom shipments—paid by central and field resources—have increased significantly from 233 million units in calendar year 2002 to 550 million units expected by final shipment in 2004.

Question. The Administration declined to apply the Mexico City Policy to HIV/AIDS funds, but there is still confusion in the field about this. Can you clarify for U.S. officials and foreign NGOs that there is no legal impediment to supporting a foreign NGO for AIDS prevention or treatment efforts, even if that organization would be barred under Mexico City from receiving family planning funds?

Answer. As you note, the Mexico City Policy applies only to assistance for family planning activities by foreign non-governmental organizations, not to assistance for HIV/AIDS funding or other health activities that do not involve assistance for family planning. The President’s extension last year of the Mexico City Policy to State Department programs expressly did not apply to HIV/AIDS assistance. Any group, subject to other relevant provisions of U.S. law, will be eligible to apply for HIV/AIDS funding under the President’s Emergency Plan.

Question. The Statement of Managers accompanying the Fiscal Year 2004 Foreign Operations Act requires you to report back to us by April 1 (60 days after enactment) on how much the Administration will spend this year on AIDS prevention activities and what amount of that will go towards “abstinence until marriage” programs. As far as I know, the report has not been submitted, or am I mistaken? When will we get it?

A provision in the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003 requires that at least one-third of all global HIV/AIDS prevention funds be set aside for “abstinence-until-marriage” programs. When Senator Feinstein offered an amendment to the Fiscal Year 2004 Foreign Operations Appropriations bill to clarify the congressional intent of the provision, you wrote a letter to Senator McConnell that was read on the Senate floor expressing opposition on the grounds that it would have restricted the administration’s flexibility and undermined your ability to implement the full variety of abstinence until marriage approaches.

How exactly do you define an “abstinence-until-marriage” program? Was this definition available during debate on the Fiscal Year 2004 Foreign Operations Appro-

priations bill? If not, why were you so sure that Senator Feinstein's amendment would have undermined your ability to fund the full variety of abstinence until marriage approaches?

If a program is successful in leading to increased abstinence with a comprehensive message that places a priority, rather than exclusive, emphasis on abstinence, would it be eligible for funds under the one-third earmark?

Based on your experience, is it appropriate to devote one-third of prevention funds to abstinence until marriage programs? If so, what empirical evidence do you base that on?

Answer. First, the Office of the U.S. Global AIDS Coordinator apologizes for the delay in submitting the report in question to Congress. The Office is working on completing the report and submitting it to Congress within the next several weeks.

Under the Emergency Plan for AIDS Relief, the "ABC" model (Abstinence, Be Faithful, and, when appropriate, correctly and consistently use of Condoms) will support behavior change for the prevention of the spread of HIV. The Emergency Plan will balance and target the application of A, B, and C interventions according to the needs and specific circumstances of different populations and individuals.

The success of the ABC model in countries such as Uganda, Zambia, and Ethiopia, among others, has demonstrated that promoting behavior change and healthy lifestyles, including abstinence and delayed sexual initiation, faithfulness and fidelity in marriage and other committed relationships, reduction in the number of partners, consistent and correct use of condoms, and avoidance of substance abuse, has been and can be successful in preventing the spread of HIV/AIDS.

Abstinence-until-marriage programs, as part of a comprehensive prevention approach, should appeal to the specific needs of specific groups. For example, in many countries the average age of marriage is 17 or 18. Once married, a message underlining the importance of faithfulness is more appropriate than an abstinence-only approach that would be appropriate for unmarried, single, school-age youth. Reliable data exists to show that youth can and do respond to abstinence-until-marriage messages and programs, and that delaying sexual activity and being faithful to one partner is not only protective for young people but can also have widespread impact on the growth of the HIV/AIDS pandemic.

As such, under the Emergency Plan for AIDS Relief, abstinence-until-marriage programs will include two goals:

- Encouraging individuals to be abstinent from sexual activity outside of marriage as a way to be protected from exposure to HIV and other sexually transmitted infections (STIs). These activities or programs will promote the following:
 - Importance of abstinence in reducing HIV transmission among unmarried individuals;
 - Decision of unmarried individuals to delay sexual activity until marriage;
 - Development of skills in unmarried individuals for practicing abstinence; and
 - Adoption of social and community norms that support delaying sex until marriage and that denounce forced sexual activity among unmarried individuals.
- Encouraging individuals to practice fidelity in sexual relationships, including marriage, as a way to reduce risk of exposure to HIV. These activities or programs will promote the following:
 - Importance of faithfulness in reducing the transmission of HIV among individuals in long-term sexual partnerships, including marriage;
 - Elimination of casual sexual partnerships;
 - Development of skills for sustaining marital fidelity, including the ability to voluntarily seek counseling and testing to know the serostatus of persons in relationship;
 - Endorsement of social and community norms supportive of refraining from sex outside of marriage, partner reduction, and marital fidelity using strategies that respect and respond to local customs and norms; and,
 - Diffusion of social and community norms that denounce forced sexual activity in marriage or long-term partnerships.

Question. The President's Emergency Global AIDS Plan does not ensure that additional funds will be available for developing safe and effective microbicides. The plan appears to leave this to the discretion of HHS and NIH. Yet NIH spends barely 2 percent of its HIV/AIDS research budget on microbicides.

Given that married women who get infected from their husbands urgently need options like microbicides, what if anything do you plan to do to mobilize more funds for this research?

Answer. Microbicides, once successfully developed, will help reduce the transmission of HIV/AIDS. Under the Emergency Plan, the National Institutes of Health (NIH) within the U.S. Department of Health and Human Services (HHS) is pur-

suings a comprehensive program for discovering, developing, testing, and evaluating microbicides for HIV prevention. HHS/NIH is the major federal sponsor of microbicide research and development. The Emergency Plan provides opportunities for HHS/NIH to expand its HIV Prevention Trials Network, a worldwide network of clinical trial sites established to evaluate the high priority area of safety and efficacy of non-vaccine HIV prevention interventions such as microbicides. As we use the tools available today to bring immediate relief to the millions suffering from consequences of HIV/AIDS, we will continue to pursue strategies, such as microbicides, that will allow us to make greater strides against this disease in the future.

We appreciate the concerns voiced by many about the vulnerabilities of women and girls to HIV/AIDS, including women coerced or forced to have sex, and who have few options for negotiating sex with their male partners. There is increasing recognition that women and girls represent nearly half of all HIV infections worldwide and that the disease disproportionately affects them in many ways. HHS/NIH supports an extensive AIDS research portfolio on women and girls. The President preceded his announcement of the Emergency Plan by his announcement in June 2002 of his \$500 million International Mother-and-Child HIV Prevention Initiative for Africa and the Caribbean. That initiative, now part of the Emergency Plan, is intended to treat one million women annually and reduce mother-to-child transmission of HIV by 40 percent within five years or less in target countries.

Several U.S. Government agencies, including the U.S. Agency for International Development (USAID) and the U.S. Department of Health and Human Services (HHS), are working with women's organizations, public health groups, and others to define mechanisms to address even better the gender dimensions of the HIV/AIDS pandemic. For example, USAID is supporting policy changes, research and interventions that address issues related to gender and HIV/AIDS and seeks to reduce women and girls' vulnerabilities to HIV/AIDS. Such activities include public outreach materials and peer-education programs directed toward men and boys to address cultural norms about violence and sexual promiscuity; promotion of abstinence and fidelity; research on issues related to women's vulnerability, including cross-generational sex, stigma, and gender-based violence; and identifying and training women's grassroots organizations to participate in policy making processes regarding HIV/AIDS.

Question. We have reports of preferential treatment in the allocation of U.S. funds to "faith-based" organizations. We have heard that in several instances, organizations with little or no experience in public health; with ideological or religious objections to offering information about safer sex and condoms; and whose proposals for funding received low scores under review by technical experts, nevertheless were given preference for funding over other organizations with strong technical capability and long-term experience. Can we get copies of the recent proposals and scores evaluating organizations that are receiving funding?

What specific guidelines are there to ensure that scientific, medical, and public health expertise is put above religious or ideological preferences in the granting of contracts?

Answer. In implementing the President's Emergency Plan for AIDS Relief, we have sought to fund a broad range of innovative partners, including host government agencies, non-governmental organizations, faith-based organizations, networks of persons living with HIV/AIDS and their families, and U.S. institutions, to bring not only expanded capacity but also innovative new thinking to our efforts. The Office of the Global AIDS Coordinator has provided general guidance to U.S. Government agencies in the field to foster partnerships with a broad array of organizations, including organizations that minimize administrative and other costs that do not directly contribute to prevention, treatment and care for persons in need. Guidance has also been provided that a partnering organization should not be required, as a condition of receiving assistance, to endorse or use a multi-sectoral approach to combating HIV/AIDS, or to endorse, use, or participate in a prevention method or treatment program to which the organization has a religious or moral objection. Neither should any organization advocate against any other component of the U.S. Government's programs. In reviewing funding proposals, criteria for the eligibility of applications include that organizations have a track record of experience in directly providing or assisting in providing treatment, care and prevention in the focus countries of the Emergency Plan.

Faith-based organizations were among the first responders to the international HIV/AIDS pandemic, and deliver much needed care and support for fellow human beings in need. Their reach, authority, and legitimacy—like other organizations—identify them as crucial partners in the fight against HIV/AIDS; we are committed to encouraging and strengthening such partners. No organization, secular or faith-

based, however, has received preferential treatment in funding on the basis of its affiliation or background.

Our intent in the initial, first round of grants under the Emergency Plan has been to move as quickly as possible to bring immediate relief to those who are suffering the devastation of HIV/AIDS. The Office of the Global AIDS Coordinator chose programs for funding in the first round because their recipients have existing operations among the focus countries of the Emergency Plan, have a proven track record, and have the capacity to rapidly scale up their operations and begin having an immediate impact.

By initially concentrating on scaling up existing programs that have proven experience and measurable track records, an additional 175,000 people living with HIV/AIDS in the 14 initial focus countries will begin to receive anti-retroviral treatment. Prevention through abstinence messages will reach about 500,000 additional young people, and assistance in the care of about 60,000 additional orphans will soon commence in those same programs.

Regarding copies of proposals and evaluation scores, the Office of the U.S. Global AIDS Coordinator did not contract directly for these proposals, but rather worked through our partner U.S. Government agencies—the U.S. Agency for International Development and the U.S. Department of Health and Human Services. Each has advised that federal executive guidelines establish that absent a Committee request (and the strict protections that are imposed pursuant to such release), proposals or evaluation materials are not released to Members of Congress as a matter of course when they contain (1) proprietary business confidential or “competitively useful” information and (2) protectable deliberative process and privacy information that might be publicly disclosed pursuant to such release. Please see, by reference, Federal Acquisition Regulation 5.403 and http://www.usdoj.gov/oip/foia_updates/Vol_V_1/page3.htm. Both HHS and USAID, however, have expressed their willingness to release, on an expedited basis, the requested Request for Applications (RFA), which include the evaluation criteria, and any actual awards that have been made, such awards being appropriately redacted to reflect business proprietary or privacy concerns.

Question. Our law requires recipients of U.S. funds to have a policy opposing prostitution and sex trafficking. However, Senator Frist and I made clear in a colloquy that this requirement would be satisfied if the grant agreement for United States funding states that the grantee opposes prostitution and sex trafficking, rather than by requiring the grantee to have an explicit policy to that effect. Is that colloquy being followed, both with respect to United States and foreign organizations?

Answer. As you note, Section 301(f) of the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (Public Law 108–25) states that “No funds made available to carry out this Act, or any amendment made by this Act, may be used to provide assistance to any group or organization that does not have a policy explicitly opposing prostitution and sex trafficking.” Also of note is Section 301(e), which expressly prohibits funds from being used to promote or advocate the legalization or practice of prostitution or sex trafficking; yet does allow for the provision of HIV/AIDS prevention, treatment and care services to victims of prostitution or sex trafficking.

Proper implementation of these two provisions is critical, and the Office of the U.S. Global AIDS Coordinator intends to implement the law consistent with the U.S. Government’s opposition to prostitution and related activities, especially those that contribute to trafficking in persons. To this end, Congress’s views, including the legislative history, report language and floor statements, have been informative and helpful.

To ensure that the relevant provisions of Public Law 108–25 are met, both the U.S. Department of Health and Human Services (HHS) and the U.S. Agency for International Development (USAID) require that primary grantees affirmatively certify their compliance with the applicable restrictions regarding prostitution and related activities prior to the receipt of any federal funds.

In addition, under the Emergency Plan, HHS and USAID are including the limitation on funds expressed in Section 301(e) in HIV/AIDS funded grants and requiring that primary recipients include the funding limitation in all subagreements. USAID is applying this same process for all HIV/AIDS funded contracts.

Regarding the implementation of Section 301(f), the Office of Legal Counsel (OLC) in the U.S. Department of Justice is considering the constitutional implications of the funding restrictions of Public Law 108–25, particularly Section 301(f). In provisional advice, OLC determined that Section 301(f) can only be constitutionally applied to foreign organizations when they are engaged in activities outside of the United States.

Currently, HHS and USAID are including the Section 301(f) limitation in their international HIV/AIDS funded grants, cooperative agreements, contracts and subagreements with foreign organizations. If a U.S. organization is the primary recipient of funds, they must include the Section 301(f) limitation in any subagreement with a foreign organization, as well as ensure, through contract, certification, audit, and/or any other necessary means, that the foreign organization complies with the limitation.

In addition, the Fiscal Year 2004 Foreign Operations, Export Financing and Related Programs Appropriations Act amends Section 301(f) of Public Law 108–25 by exempting the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), the World Health Organization (WHO), the International AIDS Vaccine Initiative (IAVI) and United Nations agencies from that section. Awards to these organizations include the limitation on funds expressed in Section 301(e).

Question. Ambassador Tobias, you have said that the fact that less than 7 percent of women used a condom in their last sex act with their main partner and that less than 50 percent of women have used a condom with casual partners shows that condom are not effective. Would you also say that the low abstinence rates that exist in many countries show that abstinence promotion is not effective in the general population and should therefore be abandoned?

Answer. Under the President's Emergency Plan for AIDS Relief, policy decisions will be evidence-based and will build on the best practices established in the fight against HIV/AIDS. I am committed to bringing the resources of sound science to bear in selecting and developing interventions that achieve real results. Determining which approach is best will depend upon numerous variables, including local needs and circumstances. The Office of the U.S. Global AIDS Coordinator will promote the proper application of the ABC approach through population-specific interventions that emphasize abstinence for youth, including the delay of sexual debut, fidelity for sexually active couples, and correct and consistent use of condoms by persons engaging in behaviors that put them at increased risk for HIV transmission. The success of the ABC model in countries such as Uganda, Zambia, and Ethiopia, among others, has demonstrated that promoting behavior change and healthy lifestyles, including abstinence and delayed sexual initiation, faithfulness and fidelity in marriage and other committed relationships, reduction in the number of partners, and consistent and correct use of condoms, has been and can be successful in preventing the spread of HIV/AIDS. Under the Emergency Plan, abstinence-until-marriage programs will have two goals: (1) Encouraging individuals to be abstinent from sexual activity outside of marriage, and (2) Encouraging individuals to practice fidelity in sexual relationships, including marriage, as ways to reduce risk of exposure to HIV and other sexually transmitted infections (STIs).

Abstinence from sexual intercourse or maintaining a mutually faithful long-term relationship between partners known to be uninfected is the surest way to avoid transmission of HIV and other sexually transmitted infections (STIs). Outside of those conditions, condoms have been an important and successful intervention in many places, particularly when made available in commercial and other casual sexual encounters, areas of high prevalence, or amongst those who do not know their serostatus. While no barrier method is 100 percent effective, correct and consistent use of latex condoms can reduce the risk of transmission of HIV by about 90 percent. The body of research on the effectiveness of latex condoms in reducing sexual transmission of HIV is both comprehensive and conclusive—if they are used correctly and consistently. Certainly, in many of the Emergency Plan focus countries, gender inequities and other issues may impact whether or not people can and will use condoms. However, part of our role in these countries will be to facilitate a shift in cultural norms around HIV prevention behaviors—abstinence, being faithful, and when necessary correct and consistent condom use. When cultural norms shift and prevention mechanism is available, great changes can occur. For example, Thailand slowed its explosive HIV epidemic by promoting “100 percent condom” use in brothels but at the same time discouraging men from visiting prostitutes. As a result of this policy and an accompanying public information campaign, as well as improved STI treatment services, condom use among sex workers increased to more than 90 percent, reported visits to sex workers by men declined by about half, HIV infection rates among military recruits decreased by about half, and the cases of five other STIs decreased by nearly 80 percent among brothel workers. Given the evidence around condom effectiveness, condom use programs the Emergency Plan supports will be leveraged across a range of situations in which those persons at increased risk for becoming infected by or for transmitting HIV will have access to them, and will include communication components to encourage responsible behavior.

QUESTIONS SUBMITTED BY SENATOR BARBARA A. MIKULSKI

Question. PEPFAR only covers 14 countries in Africa and the Caribbean. Other regions such as Eastern Europe, Latin America and Asia are left behind. Reports indicate that although Africa and the Caribbean have the largest rates of infection presently, however if left unaddressed, countries like China and India, with their large populations will easily overtake Africa in number of infections. For example, estimates show that by 2010, the number of HIV infections in India is predicted to rise from 4 million to 20–25 million, the current number of infections on the entire continent of Africa.

How are we looking to the future and addressing the emerging threats in other parts of the world?

Answer. The vision of the President's Emergency Plan is to turn the tide of HIV/AIDS. Recognizing that HIV is a virus that knows no borders, the Emergency Plan continues to support strengthened programming across the world in order to achieve this vision. The President's Emergency Plan includes nearly \$5 billion to support on-going bilateral HIV/AIDS programs in approximately 100 countries worldwide.

Question. In 2003, 58 percent of the 26.6 million people living with HIV/AIDS in sub-Saharan Africa were women. Young women between the ages of 15–24 in Africa and the Caribbean are 2.5 times more likely to have HIV than young men and teenage women are 5 times as likely. The vast majority of these women are identified as having only one mode of exposure to HIV—sex with their husbands.

Given that most sexually transmitted HIV infections in females occur either inside marriage or in relationships women believe to be monogamous, what targeted and appropriate prevention policy do we have that addresses this most vulnerable segment of the population?

Answer. I share your concerns about the vulnerabilities of young women to HIV/AIDS. Targeted and appropriate prevention strategies to address the vulnerability of women to exposure to HIV are integral to the President's Emergency Plan. The U.S. Five Year Global HIV/AIDS Strategy includes not only preventing seven million infections in some of the most afflicted countries in the world, but also continues bilateral, regional and multilateral efforts to prevent new infections.

Limitations in human resources and sites able to provide PMTCT are major impediments to implementing national PMTCT programs. The President's Mother and Child Initiative, now folded into the Emergency Plan, focused on the need to develop capacity to effectively scale-up programs. Through the President's International Mother and Child HIV Prevention Initiative and the Emergency Plan for AIDS Relief, the U.S. Government provided \$143 million for PMTCT activities and programs from October 1, 2002, to March 31, 2004. As a result, 14,700 health workers received training in the provision of PMTCT services and 900 health facilities received financial and technical support, which enabled the provision of a minimum package of PMTCT care, including (1) voluntary counseling and testing for pregnant women, (2) anti-retroviral prophylaxis to HIV-infected women to prevent HIV transmission, (3) counseling and support for safe infant-feeding practices, and (4) voluntary family planning counseling and referral. The focus on training and developing sites for PMTCT lays the foundation for scaling-up national programs, thus making a substantial step towards the Emergency Plan goal of averting seven million new HIV infections. Moreover, reaching women during pregnancy provides a critical opportunity for those who test negative to receive counseling to avoid infection.

PMTCT centers also foster and build healthy families by offering counseling and testing for expectant fathers. For example, the U.S. Government and the Elisabeth Glaser Pediatric AIDS Foundation support the Masaka Health Center in Rwanda. It has developed unique program to encourage couples to participate jointly in prenatal care and subsequently HIV testing. A personalized written invitation is prepared in the local language (Kinyarwanda) for all women who participate in prenatal care at the center and agree to be tested for HIV after counseling. They are invited to return with their partner the following weekend for a special session. This approach has resulted in a 74 percent HIV testing rate for male partners at Masaka, as compared to 13 percent for 12 other sites in the same program. Based on the success of this approach, the Foundation intends to introduce this concept to its other sites as part of an overall initiative to increase partner testing.

Under the Emergency Plan, we also foster approaches that recognize father/husband have a role to play as far as violence and HIV prevention are concerned. In Soweto, South Africa a PMTCT unit employed six counselors in 2003, one of whom one was an HIV-positive male who lost his baby son to HIV/AIDS. This counselor helped men talk about their disease and its consequences.

The Emergency Plan also supports activities to stimulate male involvement in HIV/AIDS prevention efforts. On March 27, 2004, a Solidarity Center in South Afri-

ca supported by the Emergency Plan organized a “Men as Partners” and voluntary counseling and testing (VCT) day for various workers unions in the community. The daylong program was designed to get men involved in preventing HIV transmission and violence against women.

Increasingly, young women and men who are sexually active are committing to a monogamous relationship. The President’s Emergency Plan Strategy supports comprehensive and effective prevention approaches that reflect the complex influences on young people’s decision-making and the need to address the broader social factors that shape their behaviors. Internationally, a number of programs have proven successful in increasing abstinence until marriage, delaying first sex, reducing the number of partners, and achieving “secondary abstinence” among sexually experienced youth.

The Emergency Plan recognizes several categories of activities as part of its rapid scale-up of prevention programs for young adults:

Scale up skills-based HIV education, especially for younger youth and girls.—We need to reach young people early, *before* they begin having sex, with skills-based HIV education that provides focused messages about the benefits of abstinence until marriage and other safe behaviors. Best practices suggest that curricula that target specific risk factors for early sexual activity in the local context, delivered through interactive methods that help young people clarify values, build communication skills and personalize risk are most effective. Ideally, programs go beyond sexuality to build on young people’s assets of character and encourage them to stay in school and plan for their futures.

Broad social discourse on safer norms and behaviors.—Communities need to mobilize to address the norms, attitudes, values, and behaviors that increase vulnerability to HIV, including multiple casual sex partners and cross-generational and transactional sex. The Emergency Plan supports groups that seek to generate public discussion about harmful social and sexual behaviors through a variety of media and other activities, at both the community and national levels.

Reinforcement of the role of parents and other protective factors.—Parents are potentially the most powerful protective factors in young people’s lives; they have great potential to guide youth toward healthy and responsible decision-making and safer behaviors. In Emergency Plan countries, where many youth have lost their parents to AIDS, other adult caregivers and mentors also have an important role to play in providing guidance to youth. The Emergency Plan will support efforts to reach out to parents and other adult caregivers to educate and involve them in issues relating to youth and HIV and to empower them by improving their communication skills in the areas of sexuality as well as broader limit-setting and mentoring.

Address sexual coercion and exploitation of young people.—Adolescents need a safe environment where they can grow and develop without fear of forced or unwanted sex, which often precludes the option of abstinence. The Emergency Plan supports psychosocial and other assistance for victims of sexual abuse. The Emergency Plan also supports efforts to target men with messages that challenge norms about masculinity and emphasize the need to stop sexual violence and coercion.

In sum, the President’s Plan recognizes that prevention is a continuum in which all members of the community the young and the mature, girls and women, and boys and men must be meaningfully engaged to prevent the spread of HIV/AIDS.

Question. There are currently 14 million people co-infected with TB and HIV. TB is the leading killer worldwide of people who die of AIDS, responsible for one third of all AIDS deaths. Fewer than half of those with HIV who are sick with TB in the 14 countries targeted in PEPFAR have access to TB treatment.

How does the PEPFAR initiative address the issue of TB co-infection?

Answer. The Office of the U.S. Global AIDS Coordinator is committed to the appropriate coordination, integration and support of tuberculosis (TB) and HIV/AIDS services and programs. As you are aware, opportunistic infections, such as TB and malaria, play a fundamental role in the overall health of HIV infected individuals. TB is frequently the first manifestation of HIV/AIDS disease, the reason many people first present themselves for medical care, and the leading killer of people with HIV/AIDS.

Since both tuberculosis treatment and HIV/AIDS treatment require longitudinal care and follow-up, successful TB programs provide excellent platforms upon which to build capacity for HIV/AIDS treatment. The Emergency Plan for AIDS Relief will support TB treatment for those who are HIV-infected and develop HIV treatment capacity in TB programs. In addition, interventions that increase the number of persons diagnosed and treated for HIV/AIDS will increase the need for TB treatment and care. Therefore, action is required to build or maintain necessary tuberculosis treatment capacity. For example, laboratories, clinical staff, community networks,

and management structures used for TB control can be upgraded to accommodate HIV/AIDS treatment. Finally, because the prevalence of HIV infection is high among persons with tuberculosis, TB programs will be important sites for HIV testing in the focus countries, and the Emergency Plan will work toward ensuring the availability of TB testing in HIV testing, treatment and care sites.

Question. The Global Fund to Fight AIDS, TB and Malaria specifically addresses co-infection issues has seen a cut in funding. How can you justify this?

Answer. The President's Emergency Plan for AIDS Relief made a pledge of \$200 million each year for the five-year period of 2004–2008. Our fiscal year 2005 request therefore remains the same as our request in fiscal year 2004. We were the first donor to make such a long-term pledge of support to the Global Fund, which together with our previous donations to the Fund still represents nearly 40 percent of all pledges and contributions through 2008.

The American people can be extremely proud of our record of support for the Global Fund, which is an integral part of the Emergency Plan for AIDS Relief. When the United States contributes to a project of the Global Fund, it means that our dollars are leveraged in these grants by a factor of two, since the United States thus far has provided one-third of all Fund monies. The Fund has so far committed \$2.1 billion to 224 grants in 121 countries and three territories. So it is in our interests, as well as the interest of all people struggling against HIV/AIDS, malaria and tuberculosis, to see to it that the Global Fund is an effective partner in the fight against these diseases.

The Global Fund nevertheless is a relatively new organization, particularly in comparison to the 20 years of bilateral HIV/AIDS programs carried out by the United States and other bilateral donors. As of May 15, 2004, the Global Fund had disbursed approximately \$311 million since the Global Fund's Board approved its first round of funding in January 2002. This compares to the first \$350 million under the President's Emergency Plan sent to our focus countries only three weeks after the program first received its funding.

This is not to criticize the Global Fund for being slow—indeed, the United States is one of the donors that has been urging the Global Fund to move carefully to ensure accountability and avoid waste. It does highlight, however, the potential effectiveness of bilateral assistance where donors already have an in-country presence.

We need both multilateral and bilateral avenues of assistance; neither the Global Fund nor bilateral donors can do it all. Other bilateral donors also need to step up with greater technical assistance to Global Fund projects, without which those projects will founder.

In addition, the United States believes that in order for funds to be effectively and efficiently disbursed, Country Coordinating Mechanisms (CCMs) and Local Fund Agents (LFAs) must actively engage in overseeing the implementation of grant activities. The United States would like to see, in particular, a stronger representation of the private sector, non-governmental organizations, and people living with the diseases on CCMs, largely chaired now by government ministries. Engaging a broader representation of various stakeholders will help reduce potential acts of corruption and will allow for a wider distribution of funds to serve more individuals in need.

The Global Fund has already announced, in advance of the June Board meeting, that Round Four proposals approved by the Technical Review Panel will not exceed the cash already on-hand, so that, at least through this Round, no funding gap exists. And we, along with other donors, believe that as a new organization, the Global Fund should not press its current capacity too far, and our position is that Round Five should not occur until late 2005 and Round Six no earlier than the following year. The Fund's first projects will not come up for review and possible renewal until August 2004, and we will have a better sense at that time of its performance record and future needs.

Question. On April 6, 2004, the Global Fund to Fight AIDS, TB and Malaria, the World Bank, UNICEF and the Clinton Foundation brokered a deal to announce that high quality AIDS medicines would be available for prices 50 percent less than currently available.

Will the President's initiative take advantage of these of these options?

Answer. It has always been our policy to provide, through the Emergency Plan, drugs that are acquired at the lowest possible cost, regardless of origin or who produces them, as long as we know they are safe, effective, and of high quality. These drugs could include brand-name products, generics or copies of brand-name products.

Our commitment from the beginning has been to move with urgency to help build the human and physical capacity needed to deliver this treatment, and to fund the purchase of HIV/AIDS drugs to provide this treatment at the most cost-effective

prices we can find—but only drugs we can assure ourselves are safe and effective. The people we are serving deserve the same assurances of safety and efficacy that we expect for our own families here in the United States. There should not be a double standard for quality and safety.

On May 16, Health and Human Services (HHS) Secretary Tommy G. Thompson and U.S. Global AIDS Coordinator Ambassador Randall L. Tobias held a joint press conference in Geneva, Switzerland, in advance of the World Health Assembly. Secretary Thompson and Ambassador Tobias made two very important announcements on these issues.

First, Secretary Thompson announced an expedited process for HHS, through its Food and Drug Administration (FDA), to review applications for HIV/AIDS drug products that combine already-approved individual HIV/AIDS therapies into a single dosage, often referred to as “fixed-dose combinations” (FDCs), and for co-packaged products, often referred to as “blister packs.” Drugs approved by HHS/FDA under this process will meet all normal HHS/FDA standards for drug safety, efficacy, and quality.

This new HHS/FDA process will include the review of applications from research-based companies that have developed already-approved individual therapies, or from companies that are manufacturing copies of those drugs for sale in developing nations. There are no true generic versions of these HIV/AIDS drugs because they all remain under intellectual property protection here in the United States. The steps taken by HHS/FDA could encourage the development of new and better therapies to help win the war against HIV/AIDS.

Second, Ambassador Tobias announced that when a new combination drug for HIV/AIDS treatment receives a positive outcome under this expedited HHS/FDA review, the Office of the U.S. Global AIDS Coordinator will recognize that evaluation as evidence of the safety and efficacy of that drug. Thus the drug will be eligible to be a candidate for funding by the Emergency Plan for AIDS Relief, so long as international patent agreements and local government policies allow their purchase. Where it is necessary and appropriate to do so, Ambassador Tobias will also use his authority to waive the “Buy American” requirements that might normally apply.

We hope HHS/FDA will receive applications as soon as possible from many companies that will want their drugs to be candidates for use in the treatment programs of the President’s Emergency Plan.

Because of the President’s Emergency Plan for AIDS Relief, and with the partnerships between the Emergency Plan and those individuals and organizations who are delivering treatment on the ground, we expect to increase the number of HIV-infected persons who are receiving treatment in our 14 focus countries by approximately 175,000. Today, patients are receiving treatment in Kenya and Uganda because of the Emergency Plan, and I expect that as we and others scale up our efforts, millions of more people will follow those who are already receiving this life-extending therapy.

Finally, we note that the most limiting factor in providing HIV/AIDS treatment is not drugs—it is the human and physical capacity in the health care systems in the countries we are seeking to assist. Many countries are desperately short of health care infrastructure and health care workers. Both are needed to deliver treatment broadly and effectively. We are focused on addressing this limitation as well.

QUESTIONS SUBMITTED BY SENATOR RICHARD J. DURBIN

Question. Mr. Ambassador, I would like to get clarification on the Administration’s position on contributions to the Global Fund for 2005.

The President’s 2005 budget provides only \$200 million for the Global Fund in 2005. This is less than half of the \$547 million Congress provided in 2004 and far less than the most conservative estimate of Global Fund need from the United States for 2005 of \$1.2 billion. The Global Fund is a critical partner in the 14 countries that are part of the President’s Emergency Plan for AIDS Relief (PEPFAR) and is needed in all the other countries that PEPFAR won’t reach (the Global Fund currently has grants in 122 countries). The Global Fund is currently the most important new funder of TB and malaria, as well as AIDS programs, globally.

(1) Mr. Ambassador, can you justify the President’s \$200 million request for the Global Fund in 2005, explaining why this amount is sufficient when it represents only 37 percent of what was appropriated for the Global Fund for 2004, only 24 percent of what the Global Fund has already raised for 2005, and only 6 percent of what the Global Fund will need in 2005 if it approves two rounds for that year?

(2) Why has the Administration proposed such severe cuts to the Global Fund?

(3) How can we provide leadership to the Fund while providing only \$200 million, only six percent? \$200 million isn't even a third of what's needed to keep existing programs running—that would be around \$530m.

(4) How will the Global Fund be able to renew existing grant awards from Rounds 1–3 and be able to award grants in Rounds 5 and 6 to the many countries left out of your 14 country initiative, yet equally needy?

(5) Will you support funding the Global Fund at a level of \$1.2 billion to meet its 2005 need?

Answer. The President's Emergency Plan for AIDS Relief made a \$200 million per year commitment of pledges for the five-year period of 2004–2008. Our fiscal year 2005 request therefore remains the same as our request in fiscal year 2004. We were the first donor to make such a long-term pledge of support to the Global Fund, which together with our previous donations to the Fund still represents nearly 40 percent of all pledges and contributions through 2008.

The American people can be extremely proud of our record of support for the Global Fund, which is an integral part of the Emergency Plan for AIDS Relief. As you note, we cannot make every country a focus country, and there are other nations equally needy. When the United States contributes to a project of the Global Fund, it means that our dollars are leveraged in these grants by a factor of two, since the United States thus far has provided one-third of all Fund monies. The Fund has so far committed \$2.1 billion to 224 grants in 121 countries and three territories. So it is in our interests, as well as the interest of all people struggling against HIV/AIDS, malaria and tuberculosis, to see to it that the Global Fund is an effective partner in the fight against these diseases.

The Global Fund nevertheless is a relatively new organization, particularly in comparison to the 20 years of bilateral HIV/AIDS programs carried out by the United States and other bilateral donors. Like all new organizations, it is quite understandably undergoing some growing pains. As of May 15, 2004, the Global Fund had disbursed approximately \$311 million to Principal Recipients since the Global Fund's Board approved its first round of funding in January 2002. This compares to the first \$350 million under the President's Emergency Plan sent to our focus countries only three weeks after the program first received its funding.

This is not to criticize the Global Fund for being slow—indeed, the United States is one of the donors that has been urging the Global Fund to move carefully to ensure accountability and avoid waste. It does highlight, however, the potential effectiveness of bilateral assistance where donors already have an in-country presence.

We need both multilateral and bilateral avenues of assistance; neither the Global Fund nor bilateral donors can do it all. Other bilateral donors also need to step up with greater technical assistance to Global Fund projects, since without which those projects will founder.

In addition, the United States believes that to disburse funds effectively and efficiently, Country Coordinating Mechanisms (CCMs) and Local Fund Agents (LFAs) must get actively engaged in overseeing the implementation of grant activities. The United States in particular would like to see a stronger representation of the private sector, non-governmental organizations, and people living with the diseases on CCMs, which are largely (approximately 85 percent) chaired by government ministries. Engaging a broader representation of various stakeholders will help reduce potential acts of corruption, and will allow for a wider distribution of funds so that more individuals in need can be served.

The Global Fund has already announced, in advance of the June Board meeting, that the two-year budgets of Round Four proposals recommended by the independent Technical Review Panel will not exceed the cash already on-hand, so that, at least through this Round, no funding gap exists. And we, along with other donors, believe that as a new organization, it might be best for the Global Fund not to press its current capacity too far, and our position is that Round Five should not occur until late 2005 and Round Six no earlier than the following year. The Global Fund's first projects will not come up for review and possible renewal until August 2004, and we will have a better sense at that time of its performance record and future financial needs.

Question. Ambassador Tobias, tuberculosis is the greatest curable infectious killer on the planet and the biggest killer of people with HIV. Treating TB in people with HIV can extend their lives from weeks to years. I am very concerned that the President's 2005 budget actually cuts TB and malaria funding by some \$46 million. And the President's AIDS initiative fails to focus on expanding TB treatment as the most important thing we can do right now to keep people with AIDS alive and the best way to identify those with AIDS who are candidates for anti-retroviral drugs.

I was just in India where TB is a currently far greater problem than HIV—though AIDS is rapidly catching up—and a new WHO report has shown that parts of the

former Soviet Union and Eastern Europe have rates of dangerous drug resistant TB 10 TIMES the global average! TB rates have skyrocketed in Africa in conjunction with HIV, and yet only one in three people with HIV in Africa who are sick with TB even have access to basic life-saving TB treatment. We are missing the boat on this issue—at our own risk! The cuts in TB funding are short-sighted and I think TB efforts should be expanded.

(6) Make it a priority to expand access to TB treatment for all HIV patients with TB and link TB programs to voluntary counseling and testing for HIV.

(7) Push to expand overall funding to fight TB to our fair share of the global effort? (The United States is currently investing about \$175 million in TB from all sources, including our contribution to the Global Fund.)

(8) Consider appointing a high-level person in your office to be the point person for TB efforts?

Answer. The Office of the U.S. Global AIDS Coordinator is committed to the appropriate coordination, integration and support of tuberculosis (TB) and HIV/AIDS services and programs across the U.S. Government. As you are aware, opportunistic infections, such as TB and malaria, are great risks to the overall health of HIV-infected individuals. TB is frequently the first manifestation of HIV/AIDS disease, the reason many people first present themselves for medical care, and the leading killer of people with HIV/AIDS.

Since both tuberculosis treatment and HIV/AIDS treatment require longitudinal care and follow-up, successful TB programs provide excellent platforms upon which to build capacity for HIV/AIDS treatment. The Emergency Plan will improve referral for TB patients to HIV testing and care, support TB treatment for those who are HIV-infected and develop HIV treatment capacity in TB programs. In addition, interventions that increase the number of persons diagnosed and treated for HIV/AIDS will increase the need for TB treatment and care. Therefore, action is required to build or maintain necessary tuberculosis treatment capacity. For example, laboratories, clinical staff, community networks, and management structures used for TB control can be upgraded to accommodate HIV/AIDS treatment. Finally, because the prevalence of HIV infection is high among persons with tuberculosis, TB programs will be important sites for HIV testing in the focus countries as well as ensuring that TB testing is available in HIV testing, treatment and care sites.

Finally, the Office of the U.S. Global AIDS Coordinator will take into consideration your suggestion for identifying an individual within the Office of the Coordinator to have specific responsibilities related to coordinating TB and HIV/AIDS efforts.

Question. Ambassador Tobias, in September 2002, the National Intelligence Council released a report that identified India, China, Nigeria, Ethiopia and Russia, countries with large populations and of strategic interest to the US, as the “next wave” where HIV is spreading rapidly. India already contains one-third of the global TB burden, and because AIDS fuels TB, TB rates will also skyrocket as AIDS spreads.

(9) Congress mandated a 15th country be included as a part of the President’s AIDS Initiative. The PEPFAR strategy report stated that this 15th country will be named shortly. When will you make a decision? Do you know what country this will be?

(10) What consideration is being given to including India as the 15th country, given the large number of HIV cases already present, the growing HIV problem that is likely to become a more generalized epidemic and India’s strategic importance?

India also has a remarkable TB program that has expanded over 40 fold in the last 5 years, and treated 3 million patients and trained 300,000 health workers. I would suggest that India’s TB program has important lessons for scale-up of AIDS treatment programs in India and globally and we should support it and use it as a model.

Answer. Consultations regarding the selection of a 15th country have been underway. As a first step, the U.S. Global AIDS Coordinator has consulted with senior officials within the Administration, including at the U.S. Agency for International Development (USAID), the U.S. Department of Health and Human Services (HHS), and the U.S. Department of State, about possible candidate countries for the 15th focus country. From this consultative process, the Coordinator’s Office has identified the following list of 39 countries by one or more of the agencies named above as a potential candidate for the 15th focus country.

EMERGENCY PLAN FOR AIDS RELIEF 15TH FOCUS COUNTRY—INITIAL CANDIDATE COUNTRIES

Albania, Armenia, Azerbaijan, Bangladesh, Belarus, Bolivia, Brazil, Burma, Cambodia, China, Croatia, Egypt, El Salvador, Estonia, Georgia, Guatemala, Honduras, India, Indonesia, Jordan, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Macedonia, Mexico, Moldova, Nepal, Nicaragua, Peru, Philippines, Romania, Russia, Tajikistan, Thailand, Turkmenistan, Ukraine, Uzbekistan, and Vietnam.

Currently, these countries are being considered in the context of the 10 standards listed below. These considerations provide a basis for comparative analysis and discussion regarding the potential candidates. It is important to note that these do not represent weighted criteria against which Ambassador Tobias will quantitatively evaluate to recommend one to the President. We do not expect that any one country will excel in all areas; instead, Ambassador Tobias and his staff are evaluating each country for its collective strengths and weaknesses.

- Severity and Magnitude of the Epidemic.*—The prevalence rate, the rate of increase in HIV infection, and the total number of people living with HIV/AIDS.
- Commitment of Host-Country Government.*—The basis of leadership's willingness to address HIV/AIDS and stigma and its desire to partner in an amplified response.
- Host-Country commitment of resource potential.*—The degree to which the host government has the capacity and the determination to make trade-offs among national priorities and resources to combat HIV/AIDS.
- Enabling Environment.*—The level of corruption, stigma, free press, state of government bureaucracies and the strength of bilateral partnerships, all of which help determine whether we can use Emergency Plan resources effectively.
- U.S. Government In-country Presence.*—Whether the country has a strong U.S. Government bilateral in-country presence through USAID and/or HHS.
- Applicability of Emergency Plan Approaches.*—Whether modes of transmission of HIV/AIDS in the host country are receptive to Emergency Plan interventions.
- Potential Impact of Emergency Plan Interventions.*—How many people we can reach and the effect of intervention on the trajectory of disease.
- Gaps in Response.*—Whether the U.S. Government's technical expertise, training, development and strengthening of health care systems and infrastructure would fill gaps in the current response.
- Existence of Other Partners.*—Whether non-governmental organizations and other partners have a substantial in-country presence and can facilitate rapid expansion of services and the efficient use of funds.
- U.S. Strategic Interests.*—The Emergency Plan is ultimately a humanitarian endeavor. At the same time, applicability of U.S. strategic interests could further the sustainability of programming, engender new sources of support, and offer increased opportunities for partnerships.

With regard to India, it is among the potential candidates for the 15th focus country. As you know, India has the second-largest population of HIV-infected persons in the world, second only to South Africa. Regardless of its selection as a 15th focus country, an amplified response is necessary to stem the potential for a generalized epidemic that would greatly increase India's HIV/AIDS burden. India has a well-developed national strategic plan to address HIV/AIDS and a comparatively large pool of health professionals to assist in its implementation.

In addition, the Emergency Plan for AIDS Relief includes nearly \$5 billion to support on-going bilateral HIV/AIDS programs in approximately 100 countries worldwide, including India. USAID and HHS are highly engaged and active in the HIV/AIDS response in India. India is a participating country in HHS' Global AIDS Program through which the Department allocated \$2.3 million for HIV/AIDS programs in India in fiscal year 2002, and \$3.6 million in fiscal year 2003. USAID allocated \$12.2 million to HIV/AIDS prevention and care activities in India in fiscal year 2002, and \$13.5 million in fiscal year 2003. Additionally, both the U.S. Departments of Defense and Labor have HIV/AIDS programs underway in India. Numerous other donors, including governments, the private sector, multilateral organizations, and foundations, also fund HIV/AIDS programs in India.

With regard to using India's tuberculosis program as a model for HIV/AIDS treatment, the President's Emergency Plan for AIDS Relief is focused on identifying and promoting evidence-based best practices in combating HIV/AIDS. The Directly Observed Therapy Short-Course (DOTS) treatment that has been so effective in India has served as a model for HIV/AIDS treatment programs in Haiti and elsewhere. One of the most important lessons drawn from the DOTS program is its use of community health workers to expand access to treatment. The network model of treatment and care promoted by the President's Emergency Plan implements this lesson

by using community health workers to expand access to HIV/AIDS treatment in rural areas where consistent access to medical health professionals is limited.

The President's Emergency Plan for AIDS Relief also recognizes the importance of local context in implementing effective HIV/AIDS treatment programs. India's human resource capacity is significantly greater than that of many focus countries of the President's Emergency Plan, as is the reach of its health care infrastructure. These advantages play a significant role in India's tuberculosis treatment success, but represent limiting factors in access to treatment in the focus countries. Thus, the Emergency Plan, while actively implementing best practices identified from the success of DOTS therapy, focuses significant resources in building human capacity and strengthening health infrastructure in the focus countries to support expanded treatment programs.

Question. In a press release of April 13, 2004, USAID announced the first round of grants made under PEPFAR with fiscal year 2004 funding. Five grants were announced for projects in just some of the 14 countries eligible for PEPFAR funding, totaling less than \$35 million. Only three of these grants—totaling just \$18 million—were directed to orphans and vulnerable children (OVC) programs. Not one of these grants exceeded \$7 million, even though all were for efforts in multiple countries.

Given the magnitude of the orphan problem, and the grave consequences it has for the children, their families and communities, and for their countries, these efforts seem far too tentative and too limited, far smaller than the effort anticipated by Congress in allocating 10 percent of fiscal year 2004 HIV/AIDS funds for OVC programs.

I am concerned that our financial support to date is too limited to effectively address the needs of rapidly growing numbers of orphans and other children affected by AIDS.

(11) Can you tell me how much of the fiscal year 2004 appropriation for HIV/AIDS has in fact been committed to date for this purpose and how much will be committed in fiscal year 2005?

(12) Can you assure me that fully 10 percent of the 2005 appropriations will be dedicated to this critical problem and that funding for OVC programs will expand significantly from what appears to be a slow and tentative beginning?

Answer. Each of the identified focus countries has submitted a Country Operational Plan (COP) for approval to Office of the U.S. Global AIDS Coordinator. Each COP describes the activities the U.S. Government will undertake for the remainder of fiscal year 2004 in that country. Once these plans are approved, the amount of fiscal year 2004 resources committed for activities to address orphans and vulnerable children will be available, and the Global AIDS Coordinator will be pleased to share the information with your office.

The United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (Public Law 108–25) provides that for fiscal years 2006 through 2008 not less than 10 percent of the amounts appropriated for bilateral HIV/AIDS assistance be expended for assistance for orphans and vulnerable children affected by HIV/AIDS. The Office of the U.S. Global AIDS Coordinator is committed to meeting this funding requirement through a broad-range of activities targeted at the needs of orphans and vulnerable children. In addition, USAID has recognized the importance of funding programs to support children affected by HIV/AIDS for the past few years. USAID's programs in this area are beginning to grow significantly under the Emergency Plan. Grants for orphans and vulnerable children were some of the first announced under the Emergency Plan. These grants will provide resources to assist in the care of about 60,000 additional orphans in the Emergency Plan's 14 focus countries in Africa and the Caribbean. Approaches to care will include providing critical, basic social services, scaling up basic community-care packages of preventive treatment and safe water, as well as HIV/AIDS prevention education.

Prior to the implementation of the Emergency Plan, USAID was funding over 125 programs in 27 countries to specifically respond to the unique issues facing children affected by HIV/AIDS. In addition, USAID funds a consortium of groups who are working together as the "Hope for Africa's Children Initiative."

Question. Scale-Up: The HIV/AIDS pandemic has had an enormous impact on the world's youth. To date, 13–14 million children have been orphaned by AIDS, and that number is expected to reach more than 25 million by 2010. The virtual "tsunami" of orphans in sub-Saharan Africa will spread to new countries in Africa and to Asia as death rates from AIDS rise in those regions.

(13) Within PEPFAR and other programs, what are you currently doing to scale-up efforts as regards AIDS treatment, health care and getting these children in school?

Answer. Under the Emergency Plan for AIDS Relief, activities targeted at orphans and vulnerable children will be aimed at improving the lives of children and

families affected by HIV/AIDS. The emphasis is on strengthening communities and families to meet the needs of orphans and vulnerable children affected by HIV/AIDS, supporting community-based responses, helping children and adolescents meet their own needs, and creating a supportive social environment. Program activities could include the following:

- Training caregivers;
- Increasing access to education;
- Economic support;
- Targeted food and nutrition support;
- Legal aid;
- Support of institutional responses;
- Medical, psychological, or emotional care; and,
- Other social and material support.

Question. Yesterday Secretary Thompson announced a major shift in AIDS policy relating to anti-retroviral (ARV) drugs. It is good news that the administration has created a policy that will be more streamlined than the usual HHS/FDA process for approval of anti-retroviral (ARV) generic and combination drugs. But it also seems to be creating a parallel process to that which the World Health Organization has set up to pre-qualify generic and combination ARV drugs.

I am concerned that this policy undermines the authority of the World Health Organization, which did such an admirable job combating SARS and that we need now to be strong in fighting AIDS. It also seems a slap in the face to our European allies whose regulatory authorities are the underpinning of the WHO's pre-qualification process.

(14) Are you at all concerned at the message this sends to our partners abroad about the level of respect we are prepared to give them?

(15) How will you ensure that the WHO retains its role and has the resources to expand its provision of technical assistance?

Answer. It has always been our policy to provide, through the Emergency Plan, drugs that are acquired at the lowest possible cost, regardless of origin or who produces them, as long as we know they are safe, effective, and of high quality. These drugs could include brand-name products, generics or copies of brand-name products.

Our commitment from the beginning has been to move with urgency to help build the human and physical capacity needed to deliver this treatment, and to fund the purchase of HIV/AIDS drugs to provide this treatment at the most cost-effective prices we can find—but only drugs we can assure ourselves are safe and effective. The people we are serving deserve the same assurances of safety and efficacy that we expect for our own families here in the United States. There should not be a double standard for quality and safety.

On May 16, Health and Human Services (HHS) Secretary Tommy G. Thompson and U.S. Global AIDS Coordinator Ambassador Randall L. Tobias held a joint press conference in Geneva, Switzerland, in advance of the World Health Assembly. Secretary Thompson and Ambassador Tobias made two very important announcements that impact on these issues.

First, Secretary Thompson announced an expedited process for HHS, through its Food and Drug Administration (FDA), to review applications for HIV/AIDS drug products that combine already-approved individual HIV/AIDS therapies into a single dosage, often referred to as “fixed-dose combinations” (FDCs), and for co-packaged products, often referred to as “blister packs.” Drugs approved by HHS/FDA under this process will meet all normal HHS/FDA standards for drug safety, efficacy, and quality.

This new HHS/FDA process will include the review of applications from research-based companies that have developed already-approved individual therapies, or from companies that are manufacturing copies of those drugs for sale in developing nations. There are no true generic versions of these HIV/AIDS drugs because they all remain under intellectual property protection here in the United States. The steps taken by the HHS/FDA could encourage the development of new and better therapies to help win the war against HIV/AIDS.

Second, Ambassador Tobias announced that when a new combination drug for HIV/AIDS treatment receives a positive outcome under this expedited HHS/FDA review, the Office of the U.S. Global AIDS Coordinator will recognize that evaluation as evidence of the safety and efficacy of that drug. Thus the drug will be eligible to be a candidate for funding by the Emergency Plan for AIDS Relief, so long as international patent agreements and local government policies allow their purchase. Where it is necessary and appropriate to do so, Ambassador Tobias will also use his authority to waive the “Buy American” requirements that might normally apply.

We hope HHS/FDA will receive applications as soon as possible from many companies that will want their drugs to be candidates for use in the treatment programs of the President's Emergency Plan.

With regard to the World Health Organization (WHO), we have the highest respect for the WHO and its prequalification pilot program. However, the WHO is not a regulatory authority. We must be assured the drugs we provide meet acceptable safety and efficacy standards and are of high quality. Under the Emergency Plan, we intend to support programs that will have a sustainable positive impact on health. If the medications in question have not been adequately evaluated, have had problems with safety or cause resistance issues in the future, the patients we serve and the international community we appropriately hold us accountable. We will continue to work with the WHO and the international community on this important area.

Because of the President's Emergency Plan for AIDS Relief, and with the partnerships between the Emergency Plan and those individuals and organizations that are delivering treatment on the ground, we expect to increase the number of HIV-infected persons who are receiving treatment by approximately 175,000. Today, patients are receiving treatment in Kenya and Uganda because of the Emergency Plan, and we expect that as we and others scale up our efforts, millions of more people will follow those who are already receiving this life extending therapy.

Finally, we note that the most limiting factor in providing HIV/AIDS treatment is not drugs—it is the human and physical capacity in the health care systems in the countries we are seeking to assist. Many countries are desperately short of health care infrastructure and health care workers. Both are needed to deliver treatment broadly and effectively. We are focused on addressing this limitation as well.

Question. Ambassador Tobias, while we know that your PEPFAR mandate keeps you focused on ramping up treatment and current preventive tools as quickly as possible in the countries hit hardest by the epidemic, the unfortunate truth is that treatment is unlikely to keep up with the growth of the epidemic. The President's plan calls for putting two million people on much-needed treatment by 2008, yet millions more will have been infected by then—5 million a year, according to UNAIDS.

(16) What role do you see your office playing to catalyze efforts underway to develop and distribute a preventive vaccine?

(17) What synergies do you see between the medical infrastructure needed for providing testing and treatment, and ongoing clinical trials in the developing world?

(18) How can PEPFAR programs lay the groundwork for future delivery of vaccines and other preventive technologies like microbicides?

Answer. I am strongly supportive of the need for research and development on new technologies for preventing HIV transmission, such as a preventive HIV vaccine, microbicides, and improved means to prevent mother-to-child HIV transmission (PMTCT). The U.S. Government, through the U.S. Department of Health and Human Services (HHS), the U.S. Department of Defense, and the U.S. Agency for International Development, has been substantially engaged in biomedical and behavioral research efforts in these areas for the past 20 years. Findings from HHS/National Institutes of Health (NIH) sponsored research provide the crucial scientific basis for HIV/AIDS treatment regimens, prevention interventions, and standards of care. My office intends to continue to support and promote research through leadership in continuing to advocate for such research, and to assure that it is well-coordinated with the goals of the President's Emergency Plan for AIDS Relief.

In the field, there are a number of ways our new and expanded programs for HIV/AIDS prevention, care, and treatment will help to promote this important research into new prevention technologies. First, the core of our treatment and care activities will be implemented through the "Network Model". This model supports Central Medical Centers and other community settings where prevention research can take place in a quality health care setting, including the provision of anti-retroviral therapy and other HIV/AIDS prevention, care, and treatment (including PMTCT). Expanding these services through the Emergency Plan will provide an increased number of settings where HIV/AIDS prevention research can be supported. Second, the emphasis on "institutional twinning" (defined as matching hospitals; clinics; schools of medicine, nursing, pharmacy, public administration, and management; and other institutions in the United States and other countries with counterparts in the 14 focus countries for the purposes of training and exchanging information and best practices) primarily focused on improving the capacity to provide HIV prevention, care, and treatment, will serve to expand strong relationships among institutions that also conduct research. Third, the capacity-building supported through the Emergency Plan that develops infrastructure and trains staff will have a spillover

effect in ways that will promote research, such as training health care workers, establishing public health communications infrastructure, and improving clinical and laboratory capacity.

It is not a coincidence that it has been the same developing countries that, with assistance from the U.S. Government, first participated in extensive clinical and vaccine research efforts that also have been the most successful in fighting the HIV/AIDS epidemic, especially by translating knowledge gained from clinical research into medical practice (e.g., Thailand, Uganda, Senegal, and Brazil). A robust clinical research infrastructure can be a foundation for building excellent clinical care and making the best use of the investments of the Emergency Plan for AIDS Relief.

In addition to catalyzing research into new preventive technologies, the Emergency Plan also will lay the groundwork that will accelerate the ability to *implement* any new technologies that are found to be safe and effective. For instance, if a safe and effective HIV vaccine is identified, high-risk HIV-uninfected persons will be an appropriate target group for implementation. Such persons could be identified through the network of HIV testing sites built up through Emergency Plan investments. Likewise, if a safe and effective HIV microbicide is identified, it could be promoted widely through the same behavior change programs we are expanding to meet the HIV prevention goals of the Emergency Plan, and supplies of microbicide could be distributed through the same supply-chain management systems strengthened through Emergency Plan investments.

QUESTIONS SUBMITTED BY SENATOR MARY L. LANDRIEU

Question. (1) *Domestic Violence.*—Women make up 58 percent of the HIV/AIDS population in Africa. This higher number can be attributed to cultural vices within Africa about the reluctance permit women to take drugs to prevent mother-to-child transmissions and a high rate of domestic violence where men refuse to let women negotiate condom use, according to Human Rights Watch.

What efforts are you pursuing to overcome the cultural obstacles to effectively treat and prevent HIV/AIDS? What efforts are you undertaking to curb domestic violence so that women may have a stake in both their physical safety from abuse and their medical well-being?

Answer. Stigma and discrimination against persons living with HIV and AIDS, real or perceived, does present a significant obstacle to combating HIV/AIDS. It strengthens existing social inequalities and cultural prejudices, especially those related to gender, sexual orientation, economic status, and race. Stigma and denial also create barriers to our integrated multifaceted prevention, treatment, and care strategy.

Under the Emergency Plan for AIDS Relief, we will act boldly to address stigma and denial through three operational strategies: (1) Engage local and national political, community, and religious leaders, and popular entertainers to speak out boldly against HIV/AIDS-related stigma and violence against women, and to promote messages that address gender inequality, encourage men to behave responsibly, promote HIV testing, and support those found to be HIV-positive to seek treatment; (2) Identify and build the capacity of new partners from a variety of sectors to highlight the harm of stigma and denial and promote the benefits of greater HIV/AIDS openness; and (3) Promote hope by highlighting the many important contributions of people living with HIV/AIDS, providing anti-retroviral treatment to those who are medically eligible, and involving those who are HIV-positive in meaningful roles in all aspects of HIV/AIDS programming.

With regard to domestic violence, evidence from Uganda, Tanzania, and Zambia shows that violence against women is both a cause and consequence of rising rates of HIV infection—a cause because rape and sexual violence pose a major risk factor for women, and a consequence because studies have shown that HIV-positive women are more likely to suffer violence at the hands of a partner than those who are not infected. For many women, fear of sexual coercion and violence often precludes the option of abstinence or holds them hostage to their husband's or partner's infidelity. The Emergency Plan will work closely with communities, donors, and other stakeholders to reduce stigma, protect women from sexual violence related to HIV, promote gender equality, and build family skills through conflict resolution. The Emergency Plan will also support interventions to eradicate prostitution, sexual trafficking, rape, assault, and sexual exploitation of women and children.

Question. (2) *Orphans.*—Ambassador Tobias, as you may know, I am the Chair of the Congressional Coalition on Adoption, and I will be traveling next week to Uganda with a focus on orphans and Uganda's efforts to curb the HIV/AIDS epidemic. Last year's legislation to combat the international HIV/AIDS epidemic in-

cluded language to allocate 10 percent of U.S. funding to assist children orphaned by AIDS. The United Nations estimates we could have 20 million AIDS orphans by 2010.

Could you outline how your office plans to use its funds to benefit orphans? What efforts are you taking to make it possible for these children to be adopted?

Answer. The United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (Public Law 108-25) provides that for fiscal years 2006 through 2008 not less than 10 percent of the amounts appropriated for bilateral HIV/AIDS assistance be expended for assistance for orphans and vulnerable children affected by HIV/AIDS. The Office of the U.S. Global AIDS Coordinator is committed to meeting this funding requirement through a broad-range of activities targeted at the needs of orphans and vulnerable children. The Emergency Plan for AIDS Relief, will aim activities at improving the lives of orphans and vulnerable children affected by HIV/AIDS and their families. The emphasis is on strengthening communities and families to meet the needs of orphans and vulnerable children affected by HIV/AIDS, supporting community-based responses, helping children and adolescents meet their own needs, and creating a supportive social environment. Program activities could include the following:

- Training caregivers;
- Increasing access to education;
- Economic support;
- Targeted food and nutrition support;
- Legal aid;
- Support of institutional responses;
- Medical, psychological, or emotional care; and,
- Other social and material support.

U.S. policy is to encourage extended families to care for children who have lost their parents. If families are not available, the Emergency Plan will often provide support to communities to care for children orphaned by AIDS. For example, several programs in the focus countries are supporting the integration or re-integration of orphans and vulnerable children into their communities of origin, as well as identifying foster families in local communities to care for affected children.

Programs that are part of the Emergency Plan for AIDS Relief are coordinated with policies and strategies of host governments and are responsive to local needs. Countries and communities are at different stages of HIV/AIDS response and have unique drivers of HIV, distinctive social and cultural patterns, and different political and economic conditions. Local circumstances must inform effective interventions, and the Emergency Plan will coordinate with local efforts.

Question. (3) I mentioned, I will be traveling to Uganda next week, and Uganda has been praised for its ABC Plan, Abstinence, Be Faithful, and Condoms. Even with their successes, they still have a long way to go.

Could you please name some of the countries taking proactive steps to fight HIV/AIDS? As I mentioned, even those countries taking the right steps have a long way to go, and will need long-term assistance from the United States. Are there any efforts set up a graduation plan whereby countries will stop receiving U.S. assistance for meeting certain milestones? I worry we often set the bar too low for graduation. I see that in Eastern Europe we are curbing assistance because they are “graduating” toward democracies and market economies. What steps are being taken to make sure countries don’t graduate too soon from HIV/AIDS assistance?

Answer. All of the focus countries of the Emergency Plan for AIDS Relief are taking proactive steps to address the HIV/AIDS pandemic in their country. Examples include beginning anti-retroviral treatment pilot programs (Mozambique, Guyana), scaling up anti-retroviral treatment sites (Haiti, Namibia, South Africa, Uganda), increasing HIV testing and counseling opportunities through the expanded use of community health workers (Namibia), enhancing HIV surveillance, laboratory support, and blood-safety efforts (Tanzania), distributing culturally relevant HIV-prevention messages (Botswana) and working to effectively integrate or re-integrate orphans and vulnerable children into local communities (Haiti, Rwanda). However, as you suggest, these countries are facing many difficult challenges in fully addressing their HIV/AIDS epidemic. These challenges must be addressed before any of these countries are positioned to respond on their own.

As you know, the Emergency Plan for AIDS Relief is a \$15 billion, five-year initiative targeted to reaching the following goals across the 15 focus countries:

- Providing treatment to 2 million HIV-infected adults and children;
- Preventing 7 million new HIV infections; and,
- Providing care to 10 million people infected and affected by HIV/AIDS, including orphans and vulnerable children.

By developing and strengthening integrated HIV/AIDS prevention, treatment, and care, the Emergency Plan is focused on building local capacity to provide long-term, widespread, essential HIV/AIDS services to the maximum number of those in need. Key strategies include creating and/or enhancing the human and physical infrastructure needed to deliver care; supporting the host government and local, indigenous-led organizations in their response to their nation's epidemic; ensuring a continuous and secure supply of high-quality products to patients who need them at all levels of the health system; and coordinating with other donors to eliminate duplication of efforts and fill gaps. As the five-year initiative comes to a close, assessments will be made about the continuing need for U.S. Government bilateral support, especially in light of the host government's HIV/AIDS activities and the impact of the Global Fund to Fight AIDS, Tuberculosis, and Malaria.

Question. (4) *African Capacity to Make Its Own Drugs—Independence.*—The Bible tells us that if you give a man a fish he will eat for a day. If you teach a man to fish he will eat for a lifetime. Africa has very little capacity to treat this pandemic with its own resources. All drugs are imported and there have been reports of price gauging or the purchasing of dummy drugs.

What efforts is your office undertaking to increase Africa's capacity to make its own drugs, to create a pharmaceutical infrastructure within Africa that can go from manufacturer to clinic to patient? This should reduce the cost for drugs.

Answer. Ensuring procurement of high quality pharmaceutical products is absolutely essential for the HIV/AIDS programs under the Emergency Plan. The U.S. Department of Health and Human Services (HHS) recently announced an expedited process for U.S. Food and Drug Administration (FDA) review of applications for HIV/AIDS drug products that combine already-approved individual HIV/AIDS therapies into a single dosage—many of these products are currently made in the developing countries, including South Africa. The Office of the U.S. Global AIDS Coordinator also announced that when a new combination drug for HIV/AIDS treatment receives a positive outcome under this expedited HHS/FDA review, it will recognize that tentative approval as evidence of the safety and efficacy of that drug. Thus the drug will be eligible to be a candidate for funding by the Emergency Plan, so long as international patent agreements and local government policies allow its purchase. Where necessary and appropriate to do so, the U.S. Global AIDS Coordinator will also use his authority to waive the "Buy American" requirements that might normally apply. Second, HHS plans to announce a solicitation for a contract to provide technical assistance to regulatory authorities and pharmaceutical quality assurance. The U.S. Government will seek a contractor to perform specified tasks related to the quality assurance of HIV/AIDS-related pharmaceutical products. Final products purchased by the supply management system will meet appropriate standards for quality, safety and effectiveness. This activity will also be able to support provision of direct technical assistance to increase the capacity for quality assurance in-country and strengthen quality-testing procedures.

Question. (5) *Tulane/West Africa Health Organization.*—Congress has expressed its support for a West African AIDS Initiative involving the Economic Community of West African States (ECOWAS), the West African Health Organization (WAHO) and American schools of public health (TULANE). The objective of such an initiative would be to develop and implement a coordinated effort to provide AIDS education, prevention and treatment in the West African states. As in all African countries, the ECOWAS nations struggle with overwhelming rates of infection for HIV/AIDS, a situation that poses grave potential crises in the loss of human life among the people of Africa. What are your views on such an initiative involving the West African Health Organization, supported by ECOWAS and American schools of public health?

Answer. The scope and urgent timing for expansion of training programs places a high priority in recruiting all available, experienced institutions for the effort in fighting the global HIV/AIDS pandemic, including outstanding implementing partners like Tulane that are interested and willing to establish twinning relationships with local institutions in the 15 focus countries of the President's Emergency Plan. Tulane is already highly involved, and its involvement was recently and substantially scaled up, through the HHS University Technical Assistance Program (UTAP). We expect to depend greatly on the steadily expanding work of all such outstanding partners over the course of this Initiative.

Questions. (6) Ambassador Tobias, would you explain how you plan to ship the anti-retrovirals and other drugs needed to treat HIV/AIDS, TB and malaria to Africa? Do you intend to use containerized shipping?

(7) In light of this, to what extent do you expect the drugs to experience degradation in quality as a result of high temperatures and humidity during oceanic shipment and port clearance?

(8) What is the effect of such degradation on resistance to anti-retrovirals among the patient population?

(9) Would you agree that production of these drugs in Africa could address this problem of degradation if accompanied by stringent quality controls?

Answer. On behalf of the U.S. Global AIDS Coordinator, the U.S. Agency for International Development (USAID) plans to announce for public comment imminently a request for proposal for a supply-chain management contract. The purpose of this contract is to establish a safe, secure, reliable, and sustainable supply chain and to procure pharmaceuticals and other products needed to provide care and treatment of persons with HIV/AIDS and related infections. This contract will ask for a consortium to perform a number of tasks, including procurement, in-country assistance, logistical management information system, as well as freight forwarding. We anticipate the contractor will ensure timely, accurate, safe, and cost-effective freight-forwarding services for all products, and we will expect it to make efforts to minimize any product degradation. The contractor will conduct periodic reviews of freight-forwarding practices, and identify special or reoccurring delivery problems and devise timely and cost-effective solutions for them. In addition, the contractor will establish quality-assurance procedures to ensure that required storage and handling standards for products shipped are met, to guarantee that a safe, effective, and high-quality product reaches the patient. To make certain of that, we anticipate the contractor will devise and carry out random testing of production lots purchased by the system and released for shipment. The contractor will make efforts to purchase products that require minimal shipping times, as long as it meets the Emergency Plan's goal of procuring pharmaceuticals at the lowest possible cost while guaranteeing safety, quality and effectiveness.

Question. (10) Finally, in last year's appropriations report language, the managers encouraged you to consider a pilot program, including public-private partnerships and faith-based organizations, aimed at increasing sustainability through indigenous production of drugs in Africa. What steps, if any, have you taken to explore the possibility of producing the required drugs in Africa while respecting intellectual property rights?

Answer. Ensuring procurement of high quality pharmaceutical products is absolutely essential for the HIV/AIDS programs under the Emergency Plan. The U.S. Department of Health and Human Services (HHS) recently announced an expedited process for U.S. Food and Drug Administration (FDA) review of applications for HIV/AIDS drug products that combine already-approved individual HIV/AIDS therapies into a single dosage—many of these products are currently made in the developing countries, including South Africa. The Office of the U.S. Global AIDS Coordinator also announced that when a new combination drug for HIV/AIDS treatment receives a positive outcome under this expedited HHS/FDA review, it will recognize that tentative approval as evidence of the safety and efficacy of that drug. Thus the drug will be eligible to be a candidate for funding by the Emergency Plan, so long as international patent agreements and local government policies allow its purchase. Where necessary and appropriate to do so, the U.S. Global AIDS Coordinator will also use his authority to waive the “Buy American” requirements that might normally apply. Secondly, HHS plans to announce a solicitation for a contract to provide technical assistance to regulatory authorities and pharmaceutical quality assurance. The U.S. Government will seek a contractor to perform specified tasks related to the quality assurance of HIV/AIDS-related pharmaceutical products. Final products purchased by the supply management system will meet appropriate standards for quality, safety and effectiveness. This activity will also be able to support provision of direct technical assistance to increase the capacity for quality assurance in-country and strengthen quality-testing procedures.

Question. (11) *Fixed-Dose Combinations and Pediatric Treatment.*—Children are not small adults when it comes to medicines and HIV/AIDS is no exception. Many AIDS medicines, particularly fixed dose combinations and other non-brand medicines have yet to be tested for use by children. With 2.5 million children infected with HIV around the world, it is essential that children are not an afterthought in our care and treatment activities.

A. Will the new HHS/FDA review process require that fixed-dose combinations (FDCs), both generic and brand, be available for pediatric use?

B. How does the President's five year strategy address the special needs of children who require HIV treatment?

C. What is the Administration doing to ensure that both medical professionals and others have the necessary information, equipment and training to treat children with HIV/AIDS?

Answer. The announcement on May 16 by U.S. Health and Human Services Secretary Tommy G. Thompson and U.S. Global AIDS Coordinator Ambassador Randall L. Tobias included two important components that address these issues.

First, Secretary Thompson announced an expedited process for the U.S. Department of Health and Human Services (HHS), through its Food and Drug Administration (FDA), to review of applications for HIV/AIDS drug products that combine already-approved individual HIV/AIDS therapies into a single dosage, often referred to as “fixed-dose combinations (FDCs),” and for co-packaged products, often referred to as blister packs. Drugs HHS/FDA approves under this process will meet all normal HHS/FDA standards for drug safety, efficacy, and quality.

This new HHS/FDA process will include the review of applications from research-based companies that have developed already-approved individual therapies, or from companies that are manufacturing copies of those drugs for sale in developing nations. There are no true generic versions of these HIV/AIDS drugs because they all remain under intellectual property protection here in the United States. The steps taken by HHS/FDA could encourage the development of new and better therapies to help win the war against HIV/AIDS.

Second, Ambassador Tobias announced that when a new combination drug for HIV/AIDS treatment receives a positive outcome under this expedited HHS/FDA review, the Office of the U.S. Global AIDS Coordinator will recognize that evaluation as evidence of the safety and efficacy of that drug. Thus the drug will be eligible to be a candidate for funding by the Emergency Plan for AIDS Relief, so long as international patent agreements and local government policies allow its purchase.

We hope HHS/FDA will receive applications as soon as possible from many companies that will want their drugs, including drugs for treating children, to be candidates for use in the treatment programs of the President’s Emergency Plan.

With regard to how the President’s Emergency Plan will further address the special needs of children who require HIV treatment, you might recall that before the President announced the Emergency Plan in his January 2003 State of the Union address, in June 2002 he announced his \$500 million International Mother-and-Child HIV Prevention Initiative for Africa and the Caribbean. After more than a year of implementation, that initiative is now part of the Emergency Plan, and is intended to treat one million women annually and reduce mother-to-child transmission of HIV by 40 percent within five years or less in target countries.

With regard to ensuring that both medical professionals and others have the necessary information, equipment, and training to treat children with HIV/AIDS, under the Emergency Plan we are committed to developing sustainable HIV/AIDS healthcare networks. We recognize the limits of health resources and capacity in many, particularly rural, communities. To more effectively address that shortfall, we will build on and strengthen systems of HIV/AIDS healthcare based on the “network” model. Prevention, treatment, and care protocols will be developed, enhanced, and promoted in concert with local governments and Ministries of Health. With interventions emphasizing technical assistance and training of healthcare professionals, healthcare workers, community-based groups, and faith-based organizations, we will build local capacity to provide long-term, widespread, essential HIV/AIDS care to the maximum number of those in need.

Question. (12) Prevention of Mother-to-Child Transmission (MTCT).—The President’s Global HIV/AIDS strategy recognizes that by giving a simple dose of anti-retroviral drugs to pregnant women and to the infant shortly after delivery, we can reduce mother-to-child transmission of HIV by almost 50 percent. For fiscal year 2005, MTCT activities will be integrated and financed through the Global HIV/AIDS Initiative.

A. Out of your \$1.4 billion request, how much are you requesting for MTCT?

B. Will funding for MTCT be considered as part of the 55 percent target for treatment programs? If so, will you track spending and numbers of people covered separately for these MTCT activities?

C. In countries hardest hit by the pandemic, less than 1 percent of women have access to MTCT services. Do you have any plans to scale up existing MTCT programs? If so, how will this be implemented?

D. How will the Administration expand MTCT services to people who do not have access?

Answer. Ambassador Tobias will make fiscal year 2005 funding decisions based upon the submission of a unified annual Country Operational Plan (COP) from each of the 15 focus countries. This plan maximizes the core competencies and comparative advantages of all U.S. Government departments and agencies with in-country HIV/AIDS activities and allocates resources according to those core competencies and comparative advantages. The COPs for fiscal year 2005 will further illuminate how each focus country will harness those core competencies to reach the overall

five-year Emergency Plan goals and how the allocation of resources among departments and agencies in the annual operational plan will contribute to reaching those goals. After Ambassador Tobias has approved the COPs, the Office of the U.S. Global AIDS Coordinator will be able to determine how much of fiscal year 2005 funding to allocate to the prevention of mother-to-child transmission (PMTCT) activities.

Regarding program classification, the Emergency Plan will consider traditional PMTCT activities as prevention activities and tracked accordingly. Under the Emergency Plan, the package of care for preventing mother-to-child transmission will include counseling and testing for pregnant women; anti-retroviral prophylaxis to prevent mother-to-child transmission; counseling and support for safe infant feeding practices; and voluntary family planning counseling or referral. The Emergency Plan will consider PMTCT-plus (HIV anti-retroviral treatment for HIV-infected mothers and other members of the child's immediate family) treatment activities.

As you note, the President's International Mother and Child HIV Prevention Initiative (MTCT Initiative) has become a major pillar of the President's Emergency Plan for AIDS Relief. During the initial phase of the MTCT Initiative's programming, anti-retroviral treatment was not broadly available, and our emphasis was on saving those babies at-risk for HIV infection during childbirth and early infancy. Now, the Emergency Plan is scaling up ARV treatment programs to provide ongoing ARV therapy to communities at large.

Building on the significant work already accomplished under the MTCT Initiative in 14 of the 15 focus countries, the Emergency Plan is:

- Scaling up existing PMTCT programs by rapidly mobilizing resources;
- Providing technical assistance and expanded training for health care providers (including family planning providers, traditional birth attendants, and others) on appropriate antenatal care, safe labor and delivery practices, breastfeeding, malaria prevention and treatment, and voluntary family planning;
- Strengthening the referral links among health care providers;
- Ensuring effective supply-chain management of the range of PMTCT-related products and equipment; and,
- Expanding PMTCT programs to include HIV anti-retroviral treatment for HIV-infected mothers and other members of the child's immediate family (commonly known as "PMTCT-plus").

In addition, two key strategic principles of the Emergency Plan are the development and strengthening of integrated HIV/AIDS prevention, treatment, and care and the development of sustainable HIV/AIDS health care networks. With interventions that emphasize technical assistance and training of health care professionals, health care workers, community-based groups, and faith-based organizations, the Emergency Plan is committed to building local capacity to provide long-term, widespread, essential HIV/AIDS care to the maximum number of those in need.

Question. (13) HHS/FDA Process for Review of Fixed Dose Combination (FDC) Products.—Two days ago, Secretary Thompson announced that HHS/FDA will establish an expedited review process for products that combine individual HIV/AIDS therapies into a single pill, also known as fixed-dose combination drugs. For the Administration's global AIDS initiative to be successful, it is critically important that we are able to purchase high-quality drugs at the most affordable price. If we move quickly, we can serve larger numbers of children and adults who are in need of AIDS drugs.

A. How soon do you expect this new system to be in place, and when do you think we'll have FDCs approved for use in resource-poor nations?

B. Some countries only allow for the purchase of brand or generic drugs. For example, in South Africa you can only buy brand drugs. Do you think this new process will provide momentum for countries to allow for the purchase of both brand and generic drugs? What are we doing in this area?

C. I understand that you will also be creating a competitive procurement process to purchase medications. When will this process be in place? Do you have estimates for how much drugs might cost under this system?

Answer. Guidance proposed by the U.S. Department of Health and Human Services (HHS) through its Food and Drug Administration (FDA) to implement the rapid review process of fixed-dose combination and co-packaged HIV/AIDS drugs has outlined four scenarios for reviewing different FDC and co-packaged products. Some of the scenarios could permit approval in as little as two to six weeks after submission of a high-quality application. For companies that make products for which another firm owns the U.S. patent rights, HHS/FDA could issue a tentative approval when it finds the product meets the agency's normal safety and efficacy standards.

To obtain approval of new products, manufacturers could cite existing clinical data to demonstrate the safety and effectiveness of the individual drugs in the new combined product—and new data to show effectiveness of the new combination could

be developed quickly. HHS/FDA has pledged to work with companies to help them develop that data rapidly if they do not already have access to such data. HHS/FDA is also evaluating whether it can waive or reduce user fees, normally charged to companies making new drug applications, for products reviewed under this rapid review process.

With regard to the creation of a competitive procurement process to purchase HIV/AIDS medications under the Emergency Plan, as described in the answer to questions 6–9 above, USAID plans to announce for public comment imminently a request for proposal for a supply-chain Management contract. The purpose of this contract is to establish a safe, secure, reliable, and sustainable supply chain for the Emergency Plan and to procure pharmaceuticals and other products needed to provide care and treatment of persons with HIV/AIDS and related infections at the lowest possible cost with guaranteed safety, quality and effectiveness. This contract will include procurement, in-country assistance, logistical management information system, as well as freight forwarding.

Question. (14) a. Given that other disease treatment programs involving inexpensive drugs and treatments are still major health problems in Africa due to the lack of a human resource infrastructure (malaria being a very good example), why do you believe that the more complex to deliver anti-retroviral programs for HIV/AIDS will succeed? What needs to be in place for this effort to be successful?

Answer. A lack of human resources for health (HRH) is holding back health interventions in Africa for malaria and other health problems, even though the interventions for malaria and other are technically much cheaper and simpler than anti-retroviral treatment. The Emergency Plan needs several things to be successful:

A. Better data on the current health workforce in place in countries (both employed and unemployed), a better understanding of the underlying reasons for the dismal current status, morale and performance of HRH, and concerted short- and medium-term actions by the U.S. Government in collaboration with national governments and other donors to address those causes;

B. Short-term actions to rapidly prepare and deploy more health care workers to meet the requirements for emergency delivery of needed care [local health care workers (nationals) must be the bulwark of the response, but expatriate volunteers placed through institutional twinning arrangements can be important in assisting in emergency care and in the initial phase of building sustainable capacity for ongoing training in more complex interventions such as anti-retroviral treatment]; and

C. Medium-term actions to begin increasing the numbers of health care workers available to the expanding HIV/AIDS needs (while not damaging other important efforts such as those against malaria), and to better use scarce resources, such as doctors, nurses, pharmacists, and other cadres through realigning certain tasks to less intensively-trained staff (such as community health workers).

Each of these activities are underway as part of the Emergency Plan; all will likely need to be done in nearly all countries in a concerted fashion if the Emergency Plan is to ultimately succeed. If done properly with careful design and implementation, the Emergency Plan could begin a reversal of the serious decline in HRH seen in sub-Saharan Africa and the Caribbean over the past two decades.

Question. (14) b. Does USAID have an estimate of the additional trained individuals required to implement retro-viral programs? Have you analyzed the need for retraining current tertiary service delivery personnel for the HIV/AIDS initiatives?

Answer. The U.S. Global AIDS Coordinator's Office, in collaboration with USAID and other partners, does have preliminary estimates of the additional trained personnel needed, based on the targets proposed in the first-year plans. However, those estimates are based on crudely estimated numbers of providers already trained and in place. Moreover, they are lacking essential data such as the current attrition rate from HIV/AIDS care programs, either from brain drain, retirement, HIV/AIDS infection itself, or other reasons. A critical step over the next few months and first full year of the Emergency Plan is to establish a reliable database with estimates of: (1) the currently qualified workforce, and (2) the workforce required to meet the Emergency Plan goals for each year of the Emergency Plan. Retraining current tertiary service delivery personnel is usually the quickest route to rapidly initiating anti-retroviral treatment programs, and is part of every country's program.

Question. (14) c. There is only a handful of institutions in the United States that have a history of supporting African health training institutions. For example, Tulane University and its School of Public Health and Tropical Medicine have played a very significant role in terms of the number of African health professionals trained over the years. Are these institutions actively involved in the HIV/AIDS human resource development and training efforts?

Answer. The scope and urgent timing for expansion of training programs places a high priority in recruiting all available, experienced institutions for the effort in

combating HIV/AIDS, including outstanding implementing partners like Tulane that are interested and willing to establish twinning relationships with local institutions in the 15 focus countries of the President's Emergency Plan. Tulane is already highly involved, and their involvement was recently substantially scaled up, through the HHS University Technical Assistance Program (UTAP). We expect to depend greatly on the steadily expanding work of all such outstanding partners over the course of the Emergency Plan.

Question. (14) d. Is the Agency exploring the use of information technology as a means of getting the message for HIV/AIDS training to the local institutions as efficiently as possible?

Answer. The Office of the U.S. Global AIDS Coordinator is interested in the most cost-effective, sustainable approaches to meeting the goals of the Emergency Plan. We try to match the technological approach to the specific needs and context of the training situation, rather than the other way around. In that context, we do expect (and will pay for) information technology for training as well as to support the strengthening of networks for bi-directional communication that enhances the quality of health care. We expect exciting models for a mixture of e-learning, telemedicine, and enhanced monitoring and evaluation to emerge from our U.S. Government staff's efforts at problem-solving and building sustainable capacity in the coming years.

Question. (14) e. To what extent are capacity building efforts among appropriate African educational and research institutions being involved to create an environment that can sustain the President's initiatives?

Answer. The dual principles of cost-effectiveness and sustainability require us to conduct training predominantly through African educational and training institutions. The Emergency Plan will look for African (or Caribbean) institutions to be implementers at every opportunity, especially to have them work with their peers in other of the 15 focus countries. In the many contexts in which technical assistance from United States or third-country providers might be needed to initiate programs, a requirement of all grants will be to force international grantees to have a plan to develop capacity such that they can turn their activities over to local, in-country organizations.

CONCLUSION OF HEARINGS

Senator McCONNELL. Thank you all very much for being here. That concludes our hearing.

[Whereupon, at 12:36 p.m., Tuesday, May 18, the hearings were concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]